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Research Article

# A CROSS-SECTIONAL STUDY TO ASSESS THE KNOWLEDGE ATTITUDE PRACTICE OF PHARMACOVIGILANCE AMONG THE DENTISTS IN AN INDIAN TERTIARY CARE TEACHING DENTAL HOSPITAL IN SOUTH INDIA

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**ABSTRACT**

**Objectives:** The objectives of the study are to assess the knowledge, attitude, and practices (KAP) about pharmacovigilance in interns, postgraduates, and faculty in a tertiary care teaching dental hospital.

**Methods:** A self-governed KAP survey questionnaire was conducted among interns, postgraduates, and faculty in a tertiary care teaching dental hospital. The KAP questionnaire consists of a total of 20 questions about pharmacovigilance.

**Results:** A total of 58 interns, 26 postgraduates, and 42 faculties have participated in this study. Question 1 inquired about the definition of pharmacovigilance and 31 (53.45%) interns, 20 (76.92%) postgraduates, and 34 (80.95%) faculty were given correct responses. Question 11 queried about the WHO online database for reporting adverse drug reactions (ADRs). Response rates for Question 11 from interns were 20 (34.48%), postgraduates were 15 (57.69%), and faculty was 26 (61.90%). Question 20 quizzed regarding training on how to report ADRs in which 22 (37.93%) interns, 24 (92.30%) postgraduates, and 42 (100%) faculty stated that they were trained on how to report ADR.

**Conclusion:** The majority of interns, postgraduates, and faculty had good knowledge, attitude, and practice about pharmacovigilance. Comparatively, faculty had more knowledge, attitude, and practice about pharmacovigilance among interns, postgraduates, and faculty. Prime reasons for underreporting ADR were a shortage of time to report and the difficulty to conclude whether ADR has occurred or not.

**Keywords:** Adverse drug reaction, Pharmacovigilance, Dentists.

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## INTRODUCTION

Adverse drug reaction (ADR) was defined as "any response to a drug that is noxious and unintended and occurs at doses used in man for the prophylaxis, diagnosis, or therapy of disease or for modification of physiological function." It excludes adverse reactions due to drug overdose (poisoning), drug abuse, and therapeutic errors [1]. Adverse effects are not limited, and an incidence of 10–25% has been registered in different clinical settings [2]. Pharmacovigilance is concerned with the detection, collection, assessment, monitoring, and prevention of adverse drug effects endured with the use of pharmaceutical preparations [3].

The high rate of underreporting of ADR is an important concern that hindrance the detection of serious ADRs, and subsequently, it has a major negative impact on public health. To overcome this problem, the Ministry of Health and Family Welfare, Government of India, has initiated the National Pharmacovigilance Program [4]. In India, every health-care professional inclusive of doctors, nurses, and pharmacists can report an ADR to the National Coordination Centre, Ghaziabad. Health-care professionals need to notice how to report and where to report an ADR. The vital participation of health-care professionals in the pharmacovigilance program can enhance ADR reporting [5]. In recent times, reporting of ADRs has been the principal cause of withdrawal of numerous drugs, namely rofecoxib, cisapride, and terfenadine [6]. Adverse reaction monitoring and reporting are essential in recognizing the adverse reaction tendency and curtailing or restraining harm to patients occurring from their drugs [7]. Dentists were also an important part of health-care facilities as they commonly prescribe medications such as non-steroidal anti-inflammatory drugs, antibiotics, local anesthetics, and various dental materials. There are very few studies about the awareness regarding pharmacovigilance among dentists, so this study was undertaken to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among interns, postgraduates, and faculty in a tertiary care teaching dental hospital in South India.

## METHODS

A self-governed KAP survey questionnaire was designed and validated using an approach established by Lynn [8], and the study was conducted among interns, postgraduates, and faculty in a tertiary care teaching dental hospital in South India. KAP questionnaire (Appendix I) consists of 20 questions out of which question number 1–12 was knowledge-based, question number 10 matched the following, question number 13–17 was attitude-based, and question number 18–20 was practicing-based questions, designed concretely to respond to the awareness about pharmacovigilance [9].

Participation was voluntary those who were willing to answer all the questions in the questionnaire were included in this study and those participants with partially filled questionnaires were ruled out from the study. A total of 58 interns, 26 postgraduates, and 42 faculties have participated in this study. The certificate from the institutional ethics committee was obtained and informed consent was taken from the participants before collecting the data.

## RESULTS

The results of the study will be tabulated in the following manner.

**Correct Response***

Table 1 shows interns 58, postgraduates was 26, and 42 members of the faculty participated in this study. Question 1 inquired about the definition of pharmacovigilance and 31 (53.45%) of interns, 20 (76.92) of postgraduates, and 34 (80.95) of faculty were given correct responses. Question 2 queried the important purpose of pharmacovigilance and 34 (58.62) interns, 19 (73.07) postgraduates, and 35 (83.33) faculty were given correct responses. Correct response rates for Question 3 from interns, postgraduates, and faculty were 42 (72.41), 22 (84.61), and 38 (90.47), respectively. In the case of Question 4, 20 (34.48) interns,

**Table 1: Knowledge, attitude, and practice of the interns, postgraduates, and faculty toward pharmacovigilance questionnaires**

| S. No | Q KAP items | Interns n=58 (%) | Postgraduates n=26 (%) | Faculty n=42 (%) |
|---|---|---|---|---|
| 1 | Define pharmacovigilance? | | | |
| | a. The science of monitoring ADRs happening in a hospital | 9 (15.52) | 1 (3.84) | 3 (7.14) |
| | b. The process of improving the safety of drugs | 12 (20.69) | 4 (15.38) | 4 (9.52) |
| | c. The detection, assessment, understanding, and prevention of adverse effects* | 31 (53.45) | 20 (76.92) | 34 (80.95) |
| | d. The science detects the type and incidence of ADR after the drug is marketed. | 6 (10.34) | 1 (3.84) | 1 (2.38) |
| 2 | The most important purpose of pharmacovigilance is | | | |
| | a. To identify the safety of drugs* | 34 (58.62) | 19 (73.07) | 35 (83.33) |
| | b. To calculate the incidence of ADRs | 8 (13.8) | 2 (7.69) | 2 (4.76) |
| | c. To identify predisposing factors to ADRs | 10 (17.24) | 3 (11.53) | 2 (4.76) |
| | d. To identify previously unrecognized ADRs | 6 (10.34) | 2 (7.69) | 3 (7.14) |
| 3 | Which of the following methods is commonly employed by pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market? | | | |
| | a. Meta-analysis | 4 (6.9) | 1 (3.84) | 2 (4.76) |
| | b. Post-marketing surveillance (PMS) studies* | 42 (72.41) | 22 (84.61) | 38 (90. 47) |
| | c. Population studies | 5 (8.62) | 2 (7.69) | 1 (2.38) |
| | d. Regression analysis | 7 (12.07) | 1 (3.84) | 1 (2.38) |
| 4 | A serious adverse event in India should be reported to the regulatory body within | | | |
| | a. One day | 14 (24.14) | 4 (15.38) | 6 (14.28) |
| | b. Seven calendar days | 16 (27.58) | 8 (30.76) | 8 (19.05) |
| | c. Fourteen calendar days* | 20 (34.48) | 10 (38.46) | 18 (42.85) |
| | d. Fifteen calendar days | 8 (13.79) | 4 (15.38) | 10 (23.80) |
| 5 | The international center for adverse drug reaction monitoring is located in | | | |
| | a. United States of America | 22 (37.93) | 8 (30.76) | 10 (23.80) |
| | b. Australia | 14 (24.13) | 7 (26.92) | 6 (14.28) |
| | c. France | 10 (17.24) | 4 (15.38) | 8 (19.05) |
| | d. Sweden* | 12 (20.69) | 9 (34.61) | 18 (42.85) |
| 6 | One of the following is the agency in the United States of America involved in drug safety issues | | | |
| | a. American Society of Health System Pharmacists (ASHP) | 6 (10.34) | 0 (0) | 3 (7.14) |
| | b. United States Food and Drug Administration* (US FDA) | 39 (67.24) | 21 (80.76) | 32 (76.19) |
| | c. American Medical Association (AMA) | 6 (10.34) | 2 (7.69) | 6 (14.28) |
| | d. American Pharmaceutical Association (APA) | 7 (12.06) | 3 (11.53) | 1 (2.38) |
| 7 | One of the following is a major risk factor for the occurrence of maximum adverse drug reactions | | | |
| | a. Arthritis | 10 (17.24) | 5 (19.23) | 8 (19.04) |
| | b. Renal failure * | 16 (27.58) | 14 (53.84) | 30 (71.43) |
| | c. Visual impairment | 20 (34.48) | 4 (15.38) | 2 (4.76) |
| | d. Vacuities | 12 (20.69) | 3 (11.53) | 2 (4.76) |
| 8 | In India which regulatory body is responsible for monitoring ADRs? | | | |
| | a. Indian Pharmacopoeia Commission* | 31 (53.44) | 19 (73.07) | 32 (76.19) |
| | b. Indian Institute of Sciences | 12 (20.69) | 3 (11.53) | 4 (9.52) |
| | c. Pharmacy Council of India | 8 (13.79) | 3 (11.53) | 4 (9.52) |
| | d. National Medical Council | 7 (12.06) | 1 (3.84) | 2 (4.76) |
| 9 | Which of the following scales is most used to establish the causality of an adverse drug reaction? | | | |
| | a. Hartwig scale | 20 (34.48) | 6 (23.07) | 6 (14.28) |
| | b. Naranjo algorithm* | 24 (41.38) | 14 (53.84) | 28 (66.66) |
| | c. Schumock and Thornton scale | 12 (20.69) | 4 (15.38) | 5 (11.90) |
| | d. Karch and Lasagna scale | 2 (3.45) | 2 (7.69) | 3 (7.14) |
| 10 | Match the ADR reporting systems to the respective countries (number of correct responses given from N = 58,26,42, respectively, for each answer) | | | |
| | a. Yellow card – United Kingdom* | 26 (44.83) | 14 (53.84) | 19 (45.24) |
| | b. Green card – Scotland* | 28 (48.27) | 12 (46.15) | 22 (52.38) |
| | c. ADR reporting Form – India* | 34 (58.62) | 22 (84.61) | 34 (80.95) |
| | d. Blue card – Australia* | 19 (32.75) | 14 (53.84) | 21 (50) |
| 11 | Which one of the following is the "WHO online database" for reporting adverse drug reactions? | | | |
| | a. Adverse Drug Reaction Advisory Committee | 18 (31.03) | 6 (23.07) | 8 (19.04) |
| | b. Medsafe | 8 (13.79) | 4 (15.38) | 2 (4.76) |
| | c. Vigi Base* | 20 (34.48) | 15 (57.69) | 26 (61.90) |
| | d. Med watch | 12 (20.69) | 1 (3.84) | 6 (14.28) |
| 12 | The health-care professional/s responsible for reporting adverse drug reactions in a hospital is/are | | | |
| | a. Doctor | 7 (24.14) | 2 (7.69) | 3 (7.14) |
| | b. Pharmacist | 5 (8.62) | 3 (11.54) | 5 (11.90) |
| | c. Nurses | 8 (13.79) | 2 (7.69) | 3 (7.14) |
| | d. All of the above* | 38 (65.51) | 19 (73.07) | 31 (73.80) |

*(Contd...)*

**Table 1:** ***(Continued)***

| S. No | Q KAP items | Interns n=58 (%) | Postgraduates n=26 (%) | Faculty n=42 (%) |
|---|---|---|---|---|
| 13 | Which among the following factors discourages you from reporting adverse drug reactions? (Anyone only) | | | |
| | a. Non-remuneration for reporting | 3 (5.17) | 1 (3.84) | 3 (7.14) |
| | b. Lack of time to report ADR | 41 (70.69) | 22 (84.61) | 34 (80.95) |
| | c. A single unreported case may not affect the ADR database | 3 (5.17) | 1 (3.84) | 1 (23.80) |
| | d. Difficult to decide whether ADR has occurred or not | 11 (18.96) | 2 (7.69) | 4 (9.52) |
| 14 | Do you think adverse drug reaction reporting is a professional obligation for you? | | | |
| | a. Yes* | 46 (79.31) | 24 (92.30) | 38 (90.47) |
| | b. No | 0 (0) | 0 (0) | 0 (0) |
| | c. Do not know | 0 (0) | 0 (0) | 0 (0) |
| | d. Perhaps | 12 (20.69) | 2 (7.69) | 4 (9.52) |
| 15 | What is your opinion about establishing an ADR monitoring center in every hospital? | | | |
| | a. Should be in every hospital* | 42 (72.41) | 19 (73.07) | 34 (80.95) |
| | b. Not necessary in every hospital | 6 (10.34) | 3 (11.54) | 3 (7.14) |
| | c. One in a city is sufficient | 6 (10.34) | 3 (11.54) | 3 (7.14) |
| | d. Depends on the number of bed sizes in the hospitals | 4 (6.89) | 1 (3.84) | 2 (4.76) |
| 16 | Do you think reporting adverse drug reactions is necessary? | | | |
| | a. Yes* | 44 (75.86) | 22 (84.61) | 39 (92.85) |
| | b. No | 14 (24.14) | 4 (15.8) | 3 (7.14) |
| 17 | Do you think pharmacovigilance should be taught in detail to health-care professionals? | | | |
| | a. Yes | 36 (62.07) | 20 (76.92) | 38 (90.47) |
| | b. No | 22 (37.93) | 6 (23.07) | 4 (9.52) |
| 18 | Have you read any articles on the prevention of adverse drug reactions? | | | |
| | a. Yes | 30 (51.72) | 22 (84.61) | 37 (88.09) |
| | b. No | 28 (48.27) | 4 (15.38) | 5 (11.90) |
| 19 | Have you ever come across an ADR? | | | |
| | a. Yes | 56 (96.55) | 26 (100) | 42 (100) |
| | b. No | 2 (3.45) | 0 (0) | 0 (0) |
| 20 | Have you ever been trained on how to report adverse drug reactions (ADR)? | | | |
| | a. Yes | 22 (37.93) | 24 (92.30) | 42 (100) |
| | b. No | 36 (62.07) | 2 (7.69) | 0 (0) |

10 (38.46) postgraduates, and 18 (42.85) faculty were given the correct responses. Question 5 quizzed about the International Center for ADRs monitoring. Response rates for Question 5 from interns, postgraduates, and faculty were 12 (20.69), 9 (34.61), and 18 (42.85), respectively. Question 6 inquired about agencies in the United States of America involved in drug safety issues. Response rates for Question 6 from interns were 39 (67.24), postgraduates were 21 (80.76), and faculty was 32 (76.19). Question 7 sought information about major risk factors for the occurrence of maximum ADRs. Response rates for Question 7 from interns were 16 (27.58), postgraduates were 14 (53.84), and faculty was 30 (71.43). Question 8 queried which regulatory body is responsible for monitoring ADRs in India. Response rates for Question 8 from interns, postgraduates, and faculty were 31 (53.44), 19 (73.07), and 32 (76.19), respectively. Question 9 inquired about the most used causality assessment of ADRs. According to the data for Question 9, 24 (41.38) interns, 14 (53.84) postgraduates, and 28 (66.66) faculty were answered correctly. Question 10 investigated the ADR reporting system to the respective countries utilizing match the following. The correct results for the yellow card, United Kingdom, were 26 (44.83) by interns, 14 (53.84) by postgraduates, and 19 (45.24) by faculty; for green card, Scotland 28 (48.27) by interns, 12 (46.15) by postgraduates, and 22 (52.38) by faculty; for ADR reporting form, India, 34 (58.62) by interns, 22 (84.61) by postgraduates, and 34 (80.95) by faculty; and for blue card, Australia 19 (32.75) by interns, 14 (53.84) by postgraduates, and 21 (50) by faculty. Question 11 queried about the WHO online database for reporting ADRs. Response rates for Question 11 from interns were 20 (34.48), postgraduates were 15 (57.69), and faculty was 26 (61.90). Question 12 inquired about professional responsibility for reporting ADRs. The correct results for Question 12 were 38 (65.51) by interns, 19 (73.07) by postgraduates, and 31 (73.80) by faculty. Question 13 quizzed about factors that discouraged them from reporting ADRs. Lack of time to report ADR stated by 41 (70.69) interns, 22 (84.61) postgraduates, and 34 (80.95) faculty. Question 14 queried about the attitude of reporting ADRs. The response with 46 (79.31) of interns, 24 (92.30) of postgraduates, and 38 (90.47) of faculty answered correctly. Question 15 quizzed opinions about establishing ADR monitoring centers in every hospital. In the case of Question 15, 42 (72.41) interns, 19 (73.07) postgraduates, and 34 (80.95) faculty were given correct responses. Questions 16–17 sought information about the attitude of pharmacovigilance utilizing "yes" or "no" questionnaires. Question 16 was about the necessity of reporting ADR where 44 (75.86) interns, 22 (84.61) postgraduates, and 39 (92.85) faculty felt necessary to report ADR. Question 16 was regarding pharmacovigilance training for health-care people, 36 (62.07) interns, 20 (76.92) postgraduates, and 38 (90.47) faculty answered positively about training in pharmacovigilance. The aim of Question 18 was to assess health-care professionals' perceptions and practices on the prevention of ADRs. Finally, Questions 19 and 20 sought information about the practice of pharmacovigilance utilizing "yes" or "no" questionnaires.

## DISCUSSION

ADR was described as "any response to a drug that is noxious and unintended and occurs at doses used in man for the prophylaxis, diagnosis, or therapy of disease or for modification of physiological function." Pharmacovigilance is concerned with the detection, collection, assessment, monitoring, and prevention of adverse drug effects endured with the use of pharmaceutical preparations. In India, all health-care professionals including doctors, nurses, and pharmacists can report an ADR to the National Coordination Centre, Ghaziabad.

Dentists were also an important part of health-care facilities and there were very few studies about the awareness regarding pharmacovigilance among dentists, so this study was undertaken to assess the knowledge, attitude, and practice of pharmacovigilance among interns, postgraduates, and faculty in a tertiary care teaching dental hospital in South India.

As per results, the majority of interns, postgraduates, and faculty had good knowledge, attitude, and practice about pharmacovigilance. Comparatively, faculty had more knowledge, attitude, and practice about pharmacovigilance. Among interns, postgraduates, and faculty, prime reasons for underreporting ADR were the shortage of time to report and the difficulty to conclude whether ADR has occurred or not.

This study was supported by Kumar *et al*. [10] where the prime reasons for underreporting ADR were the shortage of time to report and the difficulty to conclude whether ADR has occurred or not. Kumar *et al*. [10] also stated that the knowledge and attitude aspects of pharmacovigilance of postgraduates are reasonably good, attributed to the improving awareness about ADRs.

Another study by Chatterjee *et al*. [11] also showed the same results as the present study that the factor that discouraged doctors from reporting ADRs was lack of time and types of reaction to be preferentially reported.

This study was supported by Srinivasan and Mridula [12] where 91.3% of the participants evenly agreed that pharmacovigilance should be taught in depth to health-care professionals, which is similar to the current study where 62.07% of interns,76.92% of postgraduates, and 90.47% of faculty also stated the same.

## CONCLUSION

Pharmacovigilance plays a major role in the detection, collection, assessment, monitoring, and prevention of adverse drug effects. As per this study, the majority of interns, postgraduates, and faculty in dental teaching hospitals had good knowledge, attitude, and practice about pharmacovigilance. Among interns, postgraduates, and faculty, comparatively, the faculty had more knowledge, attitude, and practice about pharmacovigilance. Nevertheless, there are challenges such as lack of time to report ADR and difficulty to conclude whether ADR has occurred or not.

We suggest that continuing educational intervention, regulatory guidelines, and stern protocols to report ADR will help interns, postgraduates, and faculty in ADR reporting to boost up Pharmacovigilance Program in India.

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## AUTHORS CONTRIBUTIONS

Naveen Pokala was the principal investigator who contributed to the conduction of the experiment, framing the proposal and acquiring approval. Vijaykumar Sayeli was bestowed as a coinvestigator and played a vital role in the conceptualization, methodology, and reviewing of the project. Sriharsha Rayam aided the study in the course of reviewing content, and analysis, final endorsement of the version to be published.

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None.

## CONFLICT OF INTEREST

None.

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**APPENDIX I**

**KAP Questionnaire**

Instructions: You are requested to give information to the best of your knowledge. Please mark the tick for the correct response.

1. Define Pharmacovigilance? (Most appropriate anyone only)
   a. The science of monitoring ADRs happening in a hospital
   b. The process of improving the safety of drugs
   c. The detection, assessment, understanding, and prevention of adverse effects
   d. The science detects the type and incidence of ADR after the drug is marketed.

2. The important purpose of Pharmacovigilance is (Most appropriate one)
   a. To identify the safety of drugs
   b. To calculate the incidence of ADRs
   c. To identify predisposing factors to ADRs
   d. To identify unrecognized ADRs

3. Which of the following methods is commonly employed by pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market?
   a. Meta-analysis
   b. Post-marketing Surveillance (PMS) studies.
   c. Population studies
   d. Regression analysis

4. A serious adverse event in India should be reported to the regulatory body within
   a. One day
   b. Seven calendar days
   c. Fourteen calendar days
   d. Fifteen Calendar days

5. The International Center for Adverse Drug Reaction Monitoring is located in
   a. United States of America
   b. Australia
   c. France
   d. Sweden

6. One of the following is the agency in the United States of America involved in drug safety issues.
   a. American Society of Health-System Pharmacists (ASHP)
   b. United States Food and Drug Administration (US FDA)
   c. American Medical Association (AMA)
   d. American Pharmaceutical Association (APA)

7. One of the following is a major risk factor for the occurrence of maximum adverse drug reactions
   a. Arthritis
   b. Renal failure
   c. Visual impairment
   d. Vacuities

8. In India which regulatory body is responsible for monitoring ADRs?
   a. Central Drugs Standard Control Organization
   b. Indian Institute of Sciences
   c. Pharmacy Council of India
   d. Medical Council of India

9. Which of the following scales is most commonly used to establish the causality of an ADR?
   a. Hartwig scale
   b. Naranjo algorithm
   c. Schumock and Thornton scale
   d. Karch and Lasagna scale

10. Match the ADR reporting systems to the respective countries (write the number in the appropriate boxes)
    1. Yellow card () India
    2. Green card () Australia
    3. ADR reporting Form () United Kingdom
    4. Blue card () Scotland

11. Which one of the following is the "WHO online database" for reporting ADRs?
    a. ADR advisory committee
    b. Medsafe
    c. Vigibase
    d. Med watch

12. The health-care professionals responsible for reporting ADR in a hospital is/are
    a. Doctor
    b. Pharmacist
    c. Nurses
    d. All of the above

13. Which among the following factors discourages you from reporting Adverse Drug Reactions?
    a. Non-remuneration for reporting
    b. Lack of time to report ADR
    c. A single unreported case may not affect the ADR database
    d. Difficult to decide whether ADR has occurred or not

14. Do you think reporting is a professional obligation for you?
    a. Yes
    b. No
    c. Do not know
    d. Perhaps

15. What is your opinion about establishing an ADR monitoring Centre in every hospital?
    a. Should be in every hospital
    b. Not necessary in every hospital
    c. One in a city is sufficient
    d. Depends on the number of bed sizes in the hospitals.

16. Do you think reporting adverse drug reactions is necessary?
    a. Yes
    b. No

17. Do you think pharmacovigilance should be taught in detail to health-care professionals?
    a. Yes
    b. No

18. Have you read any articles on the prevention of adverse drug reactions?
    a. Yes
    b. No

19. Have you ever come across an ADR?
    a. Yes
    b. No

20. Have you ever been trained on how to report Adverse Drug Reactions (ADR)?
    a. Yes
    b. No