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 hinders 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 intern, 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 13–17 was attitude-based, and question number 18–20 was practice-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, 19 (73.07) postgraduates, and 35 (83.33) faculty were given correct responses.

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

<table>
<thead>
<tr>
<th>S. No</th>
<th>Q KAP Items</th>
<th>Interns n=58 (%)</th>
<th>Postgraduates n=26 (%)</th>
<th>Faculty n=42 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Define pharmacovigilance?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>The most important purpose of pharmacovigilance is</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>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?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>A serious adverse event in India should be reported to the regulatory body within</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>The international center for adverse drug reaction monitoring is located in</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>One of the following is the agency in the United States of America involved in drug safety issues</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>One of the following is a major risk factor for the occurrence of maximum adverse drug reactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>In India which regulatory body is responsible for monitoring ADRs?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Which of the following scales is most used to establish the causality of an adverse drug reaction?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Match the ADR reporting systems to the respective countries (number of correct responses given from $N=58,26,42$, respectively, for each answer)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Which one of the following is the &quot;WHO online database&quot; for reporting adverse drug reactions?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>The health-care professional/s responsible for reporting adverse drug reactions in a hospital is/are</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Contd...)

199
<table>
<thead>
<tr>
<th>S. No</th>
<th>QAP Items</th>
<th>Interns n=58 (%)</th>
<th>Postgraduates n=26 (%)</th>
<th>Faculty n=42 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>Which among the following factors discourages you from reporting adverse drug reactions? (Anyone only)</td>
<td>a. Non-remuneration for reporting 3 (5.17)</td>
<td>1 (3.84)</td>
<td>3 (7.14)</td>
</tr>
<tr>
<td></td>
<td>b. Lack of time to report ADR 41 (70.69)</td>
<td>22 (84.61)</td>
<td>34 (80.95)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. A single unreported case may not affect the ADR database 3 (5.17)</td>
<td>1 (3.84)</td>
<td>1 (2.38)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. Difficult to decide whether ADR has occurred or not 11 (18.96)</td>
<td>2 (7.69)</td>
<td>4 (9.52)</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Do you think adverse drug reaction reporting is a professional obligation for you?</td>
<td>a. Yes* 46 (79.31)</td>
<td>24 (92.30)</td>
<td>38 (90.47)</td>
</tr>
<tr>
<td></td>
<td>b. No 0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Do not know 0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. Perhaps 12 (20.69)</td>
<td>2 (7.69)</td>
<td>4 (9.52)</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>What is your opinion about establishing an ADR monitoring center in every hospital?</td>
<td>a. Should be in every hospital* 42 (72.41)</td>
<td>19 (73.07)</td>
<td>34 (80.95)</td>
</tr>
<tr>
<td></td>
<td>b. Not necessary in every hospital 6 (10.34)</td>
<td>3 (11.54)</td>
<td>3 (7.14)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. One in a hospital is sufficient 6 (10.34)</td>
<td>3 (11.54)</td>
<td>3 (7.14)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. Depends on the number of bed sizes in the hospitals 4 (6.89)</td>
<td>1 (3.84)</td>
<td>2 (4.76)</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Do you think reporting adverse drug reactions is necessary?</td>
<td>a. Yes* 44 (75.86)</td>
<td>22 (84.61)</td>
<td>39 (92.85)</td>
</tr>
<tr>
<td></td>
<td>b. No 14 (24.14)</td>
<td>4 (15.38)</td>
<td>3 (7.14)</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Do you think pharmacovigilance should be taught in detail to health-care professionals?</td>
<td>a. Yes 36 (62.07)</td>
<td>20 (76.92)</td>
<td>38 (90.47)</td>
</tr>
<tr>
<td></td>
<td>b. No 22 (37.93)</td>
<td>6 (23.07)</td>
<td>4 (9.52)</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Have you read any articles on the prevention of adverse drug reactions?</td>
<td>a. Yes 30 (51.72)</td>
<td>22 (84.61)</td>
<td>37 (88.09)</td>
</tr>
<tr>
<td></td>
<td>b. No 28 (48.27)</td>
<td>4 (15.38)</td>
<td>5 (11.90)</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Have you ever come across an ADR?</td>
<td>a. Yes 56 (96.55)</td>
<td>26 (100)</td>
<td>42 (100)</td>
</tr>
<tr>
<td></td>
<td>b. No 2 (3.45)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Have you ever been trained on how to report adverse drug reactions (ADR)?</td>
<td>a. Yes 22 (37.93)</td>
<td>24 (92.30)</td>
<td>42 (100)</td>
</tr>
<tr>
<td></td>
<td>b. No 36 (62.07)</td>
<td>2 (7.69)</td>
<td>0 (0)</td>
<td></td>
</tr>
</tbody>
</table>

DISCUSSION

ADR was described as "any response to a drug that is nosidious 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 inADR reporting to boost Pharmacovigilance Program in India.

ACKNOWLEDGMENTS
I am grateful to the interns, postgraduates, and faculty of tertiary care dental college for their active participation in the study.

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

AUTHORS FUNDING
None.

CONFLICT OF INTEREST
None.

REFERENCES
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. Medwatch

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