Attitude of dentists toward pharmacovigilance and reporting adverse drug reactions: A cross-sectional study

S. Sudhakar, Abhishek Madhavan, Senthil Balasubramani

Department of Oral Medicine & Radiology, ASAN Memorial Dental College & Hospital, Kanchipuram, Tamil Nadu, India

Abstract

Background: Adverse drug reaction (ADR) and intentional reporting accentuate the success of pharmacovigilance. However, a literature review suggests that globally under-reporting is on the rise, and it is among all the health care professionals including dentists. Aims and Objectives: To evaluate the attitude of dentist’s toward pharmacovigilance and ADR reporting. Materials and Methods: A cross-sectional study was done utilizing a pre-tested questionnaire. The participants were selected randomly and included on a voluntary basis. The questionnaire was structured; close ended and the participants were asked to select the options of their choice. The data obtained were subjected to statistical analysis. Results: A total of 120 questionnaires were distributed, and the response rate was 83.3%. An overall level of consensus of about 45% was observed. 64% strongly agreed that reporting ADR is necessary, and 51% disagreed that reporting of only serious and unexpected reaction is necessary. There was no significance difference between gender and experience of the dentists. Conclusion: Regardless of gender, qualification, and experience, there was a moderate level of attitude among the dentists toward ADR reporting.

Keywords
Adverse drug reaction, dentist, pharmacovigilance, reporting

Introduction

According to Barker, there are three possible actions of a drug: The one you want, the one you don’t want, and the one you don’t know about. Thus, when a drug is advised efficacy and safety are the two major concerns. While the former can be quantified with relative ease; the latter cannot be because the adverse effect/reaction of a drug can be uncommon and the patients can be affected with differential intensities. Globally, adverse drug reactions (ADRs) are on the rise, and it has been estimated that 5-20% of hospitalizations are drug related and among them only 6-10% of all the ADRs are reported. This mandates every country to set up their own Pharmacovigilance Centre to address the issues related to ADRs. In India, Pharmacovigilance Programme of India and ADR monitoring centers established by Drug Controller General of India and Indian Council of Medical Research handles issue related to ADRs. Despite these efforts, it is generally believed that the Indian contribution to the “The Uppsala Monitoring Centre” (World Health Organization [WHO], Sweden) - The International Database of ADR Reports is meagre, and this is mainly due to lack of reporting culture among health care professionals. Considering this, the present study was done to evaluate the attitude of selected dentists in Chennai (South India) region toward pharmacovigilance and ADRs reporting.

Materials and Methods

A cross-sectional questionnaire survey was conducted among dentists (including both academicians and practitioners) belonging to Chennai (South India) region. Prior to initiation of the study, the ethical committee approval was obtained, and a preliminary pilot study was done among 20 dentists, to evaluate the feasibility and selection of befitting questions before final drafting of the questionnaire. The reliability and consistency were tested with Cronbach’s alpha coefficient, and it was found between 0.6 and 0.7. Following the pilot analysis and review of findings, final drafting of questions was then prepared by subject experts (pharmacologist, dentists, and statistician) on consensus.

The study subjects were selected by simple random sampling and on the voluntary basis. An informed consent was obtained from all the participants to be a part of the study. A total of 120 questionnaire were distributed, among them
16 questionnaires were incomplete and 4 subjects showed an unwillingness to participate in the study. Excluding them, the final study sample accounted to be 100. The Questionnaire prepared for the study was in English, it was in a printed format and consisted of two parts (I and II). Part I contained questions related to the demographic data of the participants such as name, age, gender, qualification (BDS/MDS), and experience in years. Mentioning of the name of study samples was not mandated, and the option of not mentioning their name was also allowed in case the subject desired not to reveal his/her identity. Part II consisted of questions that assess the attitude of the dentists toward pharmacovigilance and ADR reporting. The questionnaire consisted of 15 items which were pre-tested, structured, close-ended, and the participants were asked to select the options of their choice given in a five-point Likert scale.

The obtained data was then entered into a Microsoft excel sheet and analyzed using Statistical Package for Social Science (SPSS, IBM, Chicago, USA) version 20. Initially, descriptive statistics of the demographic data followed by characterization of the variables and differences between groups were assessed using Chi-square tests. The statistically significant level was set at <0.05 with a confidence interval of 95%.

**Results**

A total of 120 questionnaires were distributed and among them 100 responded, giving a response rate of 83.3%. Among the subjects enrolled 53% were female, 66% were postgraduates, and 57% had <5 years of experience.

With regard to frequency of cases with an adverse reaction, 76% (rarely and very rarely) stated that they have very rarely seen such cases, whereas 7% have seen commonly [Figure 1]. The majority of the participants (64%) strongly agreed that reporting ADR is necessary, and 49% strongly believed reporting ADRs is a professional obligation [Figure 2].

When questioned for ADRs linked with specific drugs, 46% strongly said it is necessary to verify that the ADR occurring due to a particular drug should be confirmed before reporting. Similarly, 51% stated that all kinds of ADRs whether minimal/severe, unexpected should be reported [Figure 2].

Correspondingly, questions focused toward curriculum of pharmacovigilance drew suggestions that 47% believed that pharmacovigilance should be included in the curriculum, and around 50% stated that it was not covered well in their curriculum [Figure 2].

Similarly, regarding ADRs reporting 51% of them stated that they do not have any idea of how to report ADRs in India and 7% said that pharmacist is one of the important health care personnel to report them. Around 37% believed that ADRs reporting can be learnt after graduation and overall 92% showed willingness to attend and update on pharmacovigilance and ADRs reporting through continuing education program. An overall level of consensus of about 45% was observed. A statistically significant difference among educational qualifications was observed \(P < 0.022\) [Table 1]. No statistical significance was observed

---

**Table 1: Educational qualification versus level of pharmacovigilance and ADRs**

<table>
<thead>
<tr>
<th>Educational qualification</th>
<th>Level of pharmacovigilance and ADRs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
<td>Moderate</td>
</tr>
<tr>
<td>UG</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>% within educational qualification</td>
<td>11.8</td>
<td>47.1</td>
</tr>
<tr>
<td>% within level of pharmacovigilance and ADRs</td>
<td>14.8</td>
<td>35.6</td>
</tr>
<tr>
<td>PG</td>
<td>23</td>
<td>29</td>
</tr>
<tr>
<td>% within educational qualification</td>
<td>34.8</td>
<td>43.9</td>
</tr>
<tr>
<td>% within level of pharmacovigilance and ADRs</td>
<td>85.2</td>
<td>64.4</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>45</td>
</tr>
<tr>
<td>% within educational qualification</td>
<td>27.0</td>
<td>45.0</td>
</tr>
<tr>
<td>% within level of pharmacovigilance and ADRs</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

* \(P<0.022\) Significant. ADR: Adverse drug reaction
either with the experience of the dentists \((P < 0.059)\) [Table 2] or their gender \((P < 0.511)\) [Table 3].

**Discussion**

The WHO defined ADR as "any noxious, unintended, and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function.”\(^6\) Globally, under-reporting of ADRs is a cause of concern and India is no exception.\(^{[7,8]}\) Hence, there is a requirement for constant training, enactment of regulations for ADR reporting, and it is recommended that all drug related issues should be governed and addressed through pharmacovigilance. By definition, pharmacovigilance is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem, particularly long term and short term adverse effects of medicines.”\(^{[9]}\)

In spite of stringent establishments of pharmacovigilance cells and despite a good knowledge of ADRs among health care professionals literature suggests that ADRs under-reporting is still prevalent.\(^{[10,11]}\) In general, among the factors associated with ADRs under-reporting few were related to knowledge and many were linked with the attitude of the health care personnel. This was summarized by Inman as the "seven deadly sins” and his description of the “sins” include: Financial incentives, legal aspects, complacency, diffidence, indifference, ignorance, and lethargy.\(^{[12]}\) Considering this, in the present study, the attitude of dentists toward pharmacovigilance and ADRs reporting was considered for evaluation.

Among the dentists approached to participate in the study, 83.3% of them responded. This response rate was higher than the studies conducted by Gupta and Udupa (77.2%) and Desai et al. (77.7%).\(^{[7,8]}\) The reason for the highest response rate in our study could be that here the investigators approached the participants in person. Second, there were only 15 questions to respond which was not consuming much of the participants time. However, the response was lesser when compared with the study conducted by Arjun et al. (100%).\(^{[13]}\)

There is a general belief that health care professionals especially dentists have poor awareness toward pharmacovigilance. The present study also showed that around 51% (either agreed or strongly agreed) of the dentists participated claimed that they have no idea of how to report ADRs to the relevant authorities. However, 94% (either agreed or strongly agreed) expressed that ADRs reporting is necessary. This is very much higher than the study conducted by Arjun et al. (72.53%). Similarly, 89% (either agreed or strongly agreed) claimed that reporting ADRs is a professional obligation. This is very much higher in comparison with Arjun et al. (35.91%).\(^{[13]}\)

With regard to pharmacovigilance related to their practice, only 7% have experienced ADRs, this is less in comparison with Arjun et al. where 34.5% of dentists in their study group have encountered patients with ADRs. The literature suggests that there is a big lacuna between ADRs experienced and reported, this has been observed in many studies and among all health care professionals. Arjun et al. have further stated that dentists and nursing staff have never reported ADRs cases during their work with institutions. The above observation is very startling given the consequences of ADRs and its impact in health care.\(^{[13]}\)

Unfortunately, we could not avail any data in support or against the statement as the study focused only toward evaluating the

---

**Table 2: Experience in years versus level of pharmacovigilance and ADRs**

<table>
<thead>
<tr>
<th>Experience in years</th>
<th>Level of pharmacovigilance and ADRs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
<td>Moderate</td>
</tr>
<tr>
<td>≤5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>17</td>
<td>20</td>
</tr>
<tr>
<td>% within experience in years</td>
<td>29.8</td>
<td>35.1</td>
</tr>
<tr>
<td>% within level of pharmacovigilance and ADRs</td>
<td>63.0</td>
<td>44.4</td>
</tr>
<tr>
<td>&gt;5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>% within experience in years</td>
<td>23.3</td>
<td>58.1</td>
</tr>
<tr>
<td>% within level of pharmacovigilance and ADRs</td>
<td>37.0</td>
<td>55.6</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>27</td>
<td>45</td>
</tr>
<tr>
<td>% within experience in years</td>
<td>27.0</td>
<td>45.0</td>
</tr>
<tr>
<td>% within level of pharmacovigilance and ADRs</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

\(P=0.059\) not significant. ADR: Adverse drug reaction

**Table 3: Gender versus level of pharmacovigilance and ADRs**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Level of pharmacovigilance and ADRs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
<td>Moderate</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>11</td>
<td>24</td>
</tr>
<tr>
<td>% within gender</td>
<td>23.4</td>
<td>51.1</td>
</tr>
<tr>
<td>% within level of pharmacovigilance and ADRs</td>
<td>40.7</td>
<td>53.3</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>16</td>
<td>21</td>
</tr>
<tr>
<td>% within gender</td>
<td>30.2</td>
<td>39.6</td>
</tr>
<tr>
<td>% within level of pharmacovigilance and ADRs</td>
<td>59.3</td>
<td>46.7</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>27</td>
<td>45</td>
</tr>
<tr>
<td>% within gender</td>
<td>27.0</td>
<td>45.0</td>
</tr>
<tr>
<td>% within level of pharmacovigilance and ADRs</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

\(P=0.511\) not significant. ADR: Adverse drug reaction
attitude of the study group. On the hindsight, our participants expressed that pharmacovigilance was not well-covered in their curriculum and showed willingness to participate in the educational program on pharmacovigilance and ADRs reporting.

As with any study, the present study also has a few limitations. The major limitation was the small number of participants and limited to a particular geographic area; thus, the findings cannot be generalized to the dental community as a whole. Secondly, the study design was a close ended questionnaire with responses given in a five-point Likert scale; hence, the scope of registering participants view if any was limited.

Conclusion

The intention of the present study was to evaluate the attitude of selected dentists about pharmacovigilance and ADRs reporting. The results suggested that majority of them agreed that ADRs reporting is important, and very few have come across cases of ADR. Regardless of gender, qualification, and experience, there was a moderate level of consensus observed among the dentists toward pharmacovigilance and ADRs reporting. The majority of them (92% in overall) showed a positive attitude toward updating themselves about ADRs through continuing education program. Further studies with larger samples at multicentric levels are suggested to authenticate our findings.

References


Questionnaire: A Survey on Dentist Opinion on Pharmacovigilance and Adverse Drug Reactions Reporting

Pharmacovigilance: According to the World Health Organization, it is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem, particularly long term and short term adverse effects of medicines”.

Adverse drug reactions (ADRs): A noxious undesirable or unintended effect of a drug. The two most common types of ADR are type A: Augmented, which is dose related effects and type B: Bizarre, in which effects related to abnormal interaction between patient and drug.

Name: ................................................................. (optional)
Degree: Under graduate/postgraduate
Experience: ...........................................................................

Kindly tick mark the correct options. Your opinion is very valuable to us.

1. Have you come across cases of adverse drug reaction (ADR) in your own practice or elsewhere?
   a. Very common
   b. Common (frequent)
   c. Uncommon (infrequent)
   d. Rare
   e. Very rare

2. Do you think reporting of adverse drug reactions (ADR) is necessary?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

3. Do you think it is a professional obligation to report adverse drug reaction?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

4. Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

5. Do you think that it is required to report only serious and unexpected reactions?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

6. Do you think pharmacovigilance should be taught to all health care students during their curriculum?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

7. Do you think the topic of pharmacovigilance was well-covered in your curriculum?
   a. Strongly agree
   b. Agree
8. Do you know how to report ADRs to the relevant authorities in India?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

9. Information on reporting ADRs should be taught well to all health care students in their curriculum.
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

10. Information on reporting ADRs shall be better learnt during internship/training/clinical posting.
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

11. Information on reporting ADRs shall be better learnt after graduation through continuing education program.
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

12. A pharmacist is one of the most important health care professionals to report ADRs.
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

13. In my opinion, reporting of known ADRs will make no significant contribution to the reporting system.
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

14. With my present knowledge, I am very well prepared to report any ADRs presenting in my practice.
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

15. To improve my knowledge on ADRs, I would like to attend a continuing education program on ADRs and its reporting.
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree