A study of knowledge, attitudes, and practice of dental doctors about adverse drug reaction reporting in a teaching hospital in India

Objective: The aim was to investigate the knowledge, attitudes, and practice of dental doctors about adverse drug reaction (ADR) reporting. Materials and Methods: In a cross-sectional study, questionnaire was administered to 95 dental doctors working in a teaching dental hospital attached to a medical college with an ADR monitoring center (AMC). Statistical Analysis Used: Descriptive statistics were used to analyze responses. The association of knowledge and attitude with respect to position of dentists was analyzed with Chi-square test. Results: The response rate and spontaneous reporting rate was found to be 61.0% and 13.7%, respectively. Important factors contributing to under reporting of ADRs include lack of awareness about AMC in the institute (81.0%) and pharmacovigilance program (72.4%), complacency (67.2%), lack of training to identify ADRs (65.5%), fear factor (63.7%), lethargy (58.6%), lack of risk perception of over the counter product related ADR (39.6%), inadequate risk perception of nonallopathic and herbal medicines (31%), indifference (27.5%) and concern that report may be wrong (27.5%). No significant difference in knowledge and attitudes of doctors with respect to position was found except for reporting of ADRs of newly marketed drugs and serious reactions to established product (P < 0.05). Conclusion: The deficiencies in knowledge and attitudes appear to be the underlying factor for under reporting by dental practitioners. It should be addressed urgently in order to increase spontaneous reporting by them.

Key words: Awareness, dental doctors, knowledge, pharmacovigilance, spontaneous reporting

INTRODUCTION

World Health Organization has defined adverse drug reaction (ADR) as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.”[9]

With availability of more and more new therapeutic interventions the risk of ADRs are also increasing. It is found that ADRs account for 4.2–30% of hospital admissions in USA and Canada[10] and 3.4% in India.[9] Similar studies from Europe reported that up to 20% of patients receiving ambulatory treatment experience ADRs, and about 10-20% of geriatric hospital admissions are due to drug-related problems.[4,5] It is also observed that risk of mortality is increased in patients who experience ADR when compared to those who did not. Moreover, ADRs
have also been found to increase hospital stay of patients by few days.[9]

Considering that between 32% and 69% of drug-related problems were reported as definitely or possibly preventable, the importance of a robust ADR monitoring mechanism cannot be over emphasized.[7]

Spontaneous reporting plays a significant role in the detection of unsuspected, serious and unusual ADRs previously undetected during various phases of clinical trial. Many drugs with potential serious harmful effects have been withdrawn from the market due to it.[6] The contribution of health professionals deserves appreciation in this regard. In order to boost spontaneous reporting by health care providers, ADRs monitoring centers (AMC) are being established across the country under Pharmacovigilance Program of India (PvPI).[9] However, under reporting remains a major challenge.[10] Only 6-10% of all ADRs have been found to be reported.[11,12] Such lower reporting of ADR is a cause of delayed detection of serious ADRs and is a potential threat to the public health at large.

Many factors related with knowledge and attitudes are responsible for under reporting by doctors. These factors have been described as “seven deadly sins” and are related with financial incentives, legal aspects, complacency (serious ADRs well documented by the time of marketing), diffidence (ADR reporting be done if it is certain), indifference (single ADR could not contribute to medical knowledge), ignorance (it is necessary to report only serious or unexpected ADR), and lethargy (lack of time and concern for extra work).[13]

Some studies have been carried out to find out the factors responsible for under reporting among medical professionals.[14-19] These factors have not been investigated especially among dental professionals in India. Dental doctors are also involved in prescribing many therapeutic interventions, including allopathic medicines like local anesthetics, antibiotics, analgesic and anti-inflammatory drugs etc., Antibiotics and analgesics are among the leading causes of ADRs.[2,20] Hence the risk of ADRs cannot be ignored in dentistry and the contribution of dentists in improving spontaneous reporting cannot be underestimated.

Therefore, the present study was planned to evaluate the knowledge and attitudes of dental doctors to ADR reporting in a dental teaching hospital attached to a medical college with an AMC in India and if possible, suggest ways of enhancing spontaneous reporting based on findings. It is anticipated that doctors with higher position should have better knowledge and attitudes toward ADR reporting.

**MATERIALS AND METHODS**

This was a cross-sectional questionnaire based study. The questionnaire was formulated taking precedence from previous studies[14,15,17-19] and structured in a manner to observe the knowledge, attitudes and practice of dental doctors toward ADR reporting and the factors that may influence reporting. As it is a noninterventional observational study, prior approval from heads of respective department was taken. The questionnaire, containing mostly closed-ended questions, was administered to dentists working in clinical departments of a dental hospital. A total of 95 dentists who were found to be available within a week were administered questionnaires. The participants were asked to strike multiple options wherever applicable. They were requested to complete the questionnaire immediately and those who were busy, were requested to return back the duly filled questionnaires within 2-3 working days in the Department of Pharmacology. Follow-up visits were also made to increase response rate.

**Statistical analysis**

The data were analyzed by statistical software GraphPad Prism version 5.0 developed by GraphPad Software, Inc. USA The descriptive statistics were used for responses to identify the knowledge and attitudes toward ADR reporting. To compare the knowledge and attitude with position, Chi-square test was applied at $P < 0.05$ significance level.

**RESULTS**

Out of 95 questionnaires administered to dentists, 59 were returned. Thirty-six doctors didn't return the questionnaire even after repeated follow-up, many of whom declined to participate in the study later on. One questionnaire was excluded due to lack of sufficient responses. Fifty eight questionnaires were found to be suitable for analysis, thus giving a response rate of 61.0%. The respondents were grouped into senior and junior cadre for comparison [Table 1].

**Table 1: Demographics, response rate and ADR reporting rate (n=58)**

| Participants                        | Frequency (%) |
|-------------------------------------|---------------|
| Age (mean±SD)                       | 28.13±5.73    |
| Senior doctors (professor, readers, lecturers) | 24 (41.3) |
| Junior doctors (postgraduates and interns) | 34 (58.6) |
| Male: Female ratio                  | 21:37 (36.2:63.7) |
| Response rate                       | 58/95 (61.0)  |
| ADR reporting rate                  | 8 (13.7)      |
| Never seen an ADR                   | 20 (34.4)     |

ADR=Adverse drug reaction, SD=Standard deviation
Average age of study population in the present study is about 28.1 years [Table 1]. This could be due to participation of more number of junior doctors in the present study. More number of females participated in the present study than males [Table 1]. This could be explained by the fact that more females are opting for career in dentistry than their counterpart.

**Knowledge of adverse drug reaction reporting**

Sixteen (27.5%) participants were aware of PvPI, while just 18.9% dentists were aware of the AMC in the institute. Majority of respondents agreed to report all ADRs of newly marketed drug (84.4%) and serious reactions of established product (87.9%). 67.2% dentists perceived that all serious ADRs are identified by the time of marketing approval. 31.0% dentists felt that all nonallopathic and herbal medicine are safe, whereas 39.6% considered that over the counter (OTC) related ADR need not be reported [Table 2].

**Attitudes to adverse drug reaction reporting**

More than 50% respondents failed to acknowledge ADR reporting as a professional obligation. 27.5% of the dentists could not perceive the significance of reporting ADR last time, 34.4% responded they never saw an ADR [Table 1].

The inter-group comparison could not find significant difference in the knowledge and attitudes of dentists except that for about reporting of ADRs of newly marketed drugs and about reporting serious reactions to established product [Table 2].

**DISCUSSION**

Various factors related with the knowledge and attitudes of dentists towards ADR reporting are presented in Table 3. The factors perceived to discourage ADR reporting are given in Table 4. The factors perceived to discourage ADR reporting are given in Table 4. The factors perceived to discourage ADR reporting are given in Table 4.

**Table 2: Evaluation of knowledge of doctors to adverse drug reaction reporting (n=58)**

| Knowledge and attitudes                                                                 | Yes (%) | No (%) |
|----------------------------------------------------------------------------------------|---------|--------|
| Awareness of pharmacovigilance program                                                  | 16 (27.5) | 42 (72.4) |
| Awareness of AMC                                                                       | 11 (18.9) | 47 (81.0) |
| All ADRs of newly marketed drug to be reported                                         | 49 (84.4)* | 9 (15.5) |
| Serious reactions of established products should be reported                            | 51 (87.9)* | 7 (12.0) |
| All serious ADRs identified by the time of marketing approval                          | 39 (67.2) | 19 (32.7) |
| All nonallopathic and herbal medicine are safe                                         | 18 (31.0) | 40 (68.9) |
| OTC related ADR need not be reported                                                  | 23 (39.6) | 35 (60.3) |

*P<0.05 (Chi-square test, senior doctors versus junior doctors). AMC=ADR monitoring center, ADR=Adverse drug reaction, OTC=Over the counter

**Table 3: Attitudes of doctors toward ADR reporting (n=58)**

| Attitudes                                                                 | Frequency (%) |
|--------------------------------------------------------------------------|--------------|
| ADR reporting is a professional obligation                                | 28 (48.2) | 6 (10.3) | 24 (41.3) |
| One ADR makes no significant contribution                                | 16 (27.5) | 27 (46.5) | 15 (25.8) |

**Table 4: Factors perceived to discourage ADR reporting (n=58)**

| Factors                                                                 | Frequency (%) |
|--------------------------------------------------------------------------|--------------|
| Difficult to decide whether or not an ADR has occurred                   | 30 (55.5)    |
| Lethargy (lack of time/concern for extra work)                           | 34 (52.6)    |
| Concern that report may be wrong                                         | 16 (27.5)    |
| Do not feel the need to report a recognized ADR                          | 8 (13.79)    |
| Fear of negative impact on practice                                      | 8 (13.79)    |
| Fear of legal and punitive actions                                       | 8 (13.79)    |
| Lack of confidence to discuss ADR with colleague                         | 6 (10.3)     |
| Fear of the negative impact on company                                  | 1 (1.78)     |
| Nonremuneration for reporting                                            | 1 (1.78)     |
doctors are attributed to under reporting of ADRs.[13] Some studies have tried to find out these factors among medical doctors.[14-18] However, these factors have not been studied among dental practitioners alone in India. Therefore, the present study was carried out to evaluate the knowledge and attitudes of dental doctors to ADR reporting in a tertiary care teaching hospital.

The lack of knowledge about existence of ADR reporting is evident by the finding that only 27.5% of dental doctors know about pharmacovigilance program and 18.9% are informed about AMC.[2] A previous study from UK found awareness about ADR reporting system in 74.6% of dental practitioners.[21] Between 30% and 90% of medical doctors have been found to be aware of ADR reporting system in other studies in India.[14-18] Currently, ADR reporting system is not completely established as India is in the process of implementing PvPI in a phased wise manner across the country. In this scenario, variations in the awareness about ADR reporting system at different locations can be anticipated. Low awareness can also be attributed to poor awareness campaign run by the local AMC, whereas high awareness can be attributed to continuous and effective awareness campaign run by the local authority. Therefore, increasing awareness about ADR reporting system among dental practitioners through effective campaign appears to be the top most immediate action required to improve spontaneous reporting. Though dental students are taught about ADR reporting during their under graduation in 2nd year. However, it is not in practice as pharmacovigilance related work has not been included in their curriculum. Hence, it is the need of the hour to include pharmacovigilance related work during undergraduate and post graduate tenure to bring ADR reporting into practice. Indeed, this will improve their awareness and will improve spontaneous reporting in the long run as well.

Although majority of the dentists agreed to report all ADRs of newly marketed drugs (84.4%) and serious ADR of established products (87.9%), but high percentage (67.2%) of them perceived that all serious ADRs are identified by the time of marketing approval! [Table 2]. Similarly in a study involving medical and dental doctors, 33.8% were unaware of risk of serious ADRs with newly marketed drugs.[22] Some serious and unusual ADRs are detected only after drug is available for use of common public after getting marketing approval. Many drugs have been withdrawn from the market in recent past due to emergence of serious reactions.[8] Failure to recognize this risk is an alarming situation which needs to be addressed urgently.

One meta-analysis has found the incidence of serious ADR to be 6.7% and fatal ADR to be 0.32%, making them among the top ten leading causes of death.[23] As Indian market is witnessing arrival of many newer drugs, delayed detection of serious ADR pose a great risk to the health. Dental practitioners should be informed about it on priority basis.

Moreover, a significant number of respondents (31.0%) opined that all nonallopathic and herbal medicines are safe. In a similar study, only 29.6% medical doctors agreed to report ADRs caused by herbal medicine, whereas another study found willingness to report ADRs from herbal and traditional medicine in 7.3% doctors.[14-15] Risk of ADRs including serious one, from herbal and traditional medicine is well recognized in scientific literature.[24] This reflects insufficient training of dentists about medicinal risks.

Twenty-three (39.6%) dentists do not feel the need to report ADR from OTC [Table 2]. Similar lack of need to report OTC related ADR was expressed by 20.6% medical doctors in another study.[25] OTC drugs form a bulk of drug consumption by the society. Although they are considered to be safer, in order to foster reporting culture and develop data base from Indian patients, pharmacovigilance program recommends reporting of all suspected ADRs including those from OTC products.[26] This should be communicated to the dentists to improve spontaneous reporting.

More than 50% respondents failed to realize ADR reporting as a professional obligation, whereas 27.59% of the dentists did not find it significant to report one ADR [Table 3]. Similar problems with attitudes have been reported by other study in which 31.8% doctors including dental practitioners could not realize the significance of reporting one ADR, while 84.1% were obliged to report ADRs.[27] Personal discussions can help to dispel misconceptions and change attitudes of doctors whereby ADR reporting is considered as a part of practice and a professional obligation toward society. Attitude that single report makes no contribution also needs correction, because every single suspected ADR helps in developing data base. Such a change in attitude will be helpful in improving spontaneous reporting in the long run.

Though fear is disclosed by 29.3% as discouraging factors [Table 4] but fear is evident from large number of respondents expressing to hide identity of prescriber and reporter (63.7%) [Table 3]. Similar observations were found in other studies involving medical professionals.[16,17] Fear is a threat to ADR reporting and can undermine PvPI. It should be removed through informing dentists that ADRs are part and parcel of drug therapy but can be prevented to a large extent through applying principles of rational therapy, as inappropriate use of drugs has been found to be the leading cause of ADRs in elderly population.[28]
Prescriber/reporter is not held responsible for ADR if he/she had followed the principles of rational therapeutics. Majority of the dentists were encouraged to report ADR if it is serious (84.4%), however 68.9%, 50%, 37.9% and 32.7% of the dentists were encouraged to report ADR if the reaction is unusual, new, well recognized and certain, respectively [Figure 1]. In a similar type of study 77.5%, 79.5% and 84.8% of medical and dental doctors were encouraged to report serious ADRs, ADRs to new drugs and unknown ADRs to old drugs respectively. PvPI recommends that all ADRs should be reported whether they are serious, nonserious, unusual, new, recognized and certain. Therefore there appears a deficiency in the knowledge and perception of dental doctors in relation to ADR reporting which should be removed in order to improve spontaneous reporting.

Difficulty in deciding whether an ADR has occurred or not (65.5%), and concern that the report may be wrong (27.5%) indicates lack of training of dentists in identifying ADRs [Table 4]. Similar responses were observed in higher proportion in a previous study in which concern that report may be wrong and difficulty in deciding ADR occurrence was reported by 80.9% and 81.8% medical doctors respectively. This deficiency can be removed by having regular interdisciplinary discussions involving clinicians and pharmacologists. Furthermore, during undergraduate and post graduate training program special attention should be given to safety profile of the drugs apart from rational therapeutics. Integrating pharmacovigilance related work in undergraduates and post graduates curriculum appears to be the need of the hour.

Personal discussion and infusing sense of responsibility toward safety of the patients whereby ADR reporting is considered as a duty will help to dispel lethargic attitude (58.6%) [Table 4] and will play a long way in the success of PvPI. Such lethargic attitudes have also been observed by other researchers.

Inter-group comparison didn’t find significant difference in the knowledge and attitudes across senior and junior doctors except that for significantly ($P < 0.05$) greater awareness among seniors about reporting ADR resulting from newly marketed drugs and serious reactions to established product ($P < 0.05$) [Table 2]. A significantly ($P = 0.003$) greater awareness about ADR reporting system was observed among dental practitioners with more years in practice, in a study done outside India. A lack of difference in knowledge and attitudes was observed in other studies involving medical faculty and post graduates. It appears that the undergraduate and post graduate training program are lacking in mentoring the doctors for the task of pharmacovigilance and a comprehensive multi-level approach is required to address this problem.

In the present study, the spontaneous reporting rate was 13.7% [Table 1]. Other studies also found lower rate of spontaneous reporting in the range of 15-19.1%. Despite high rate of ADRs in ambulatory patients, 34.4% dentists revealed that they had never seen an ADR [Table 1]. In one such study, 58.5% dental practitioners conceded that they had never seen an ADR. This is a matter of great concern and deserves immediate attention and raises the need of education and training of dental doctors about ADRs from identification to reporting, which would result in improving spontaneous reporting rate.

To summarize, important factors found to be responsible for under reporting among dental doctors in the present study include lack of awareness about AMC (81.0%), and pharmacovigilance program (72.4%), lack of risk perception of newly marketed drugs (67.2%), lack of training to identify ADR (65.5%), fear factors (63.78%), lethargy (58.6%), lack of professional obligation (51.7%), lack of risk perception about OTC products (39.6%) and nonallopathic/herbal medicine (31.0%), and lack of significance of reporting one ADR (27.5%).

Above findings suggest that under reporting of ADRs is associated with gaps in the knowledge and attitudes, which is also pointed out in other studies.

Based on the findings of the present study, the authors suggest following corrective measures to be taken to improve spontaneous reporting by dental practitioners: (a) Increase awareness about pharmacovigilance and AMC, (b) inform doctors about the risk of newly marketed drugs, OTC product and herbal medicine, (c) doctors should be encouraged to report all suspected ADR irrespective of its level of association, (d) inform doctors that drug is responsible for ADRs so a rational prescriber or reporter cannot be held responsible for it, (e) holding personal discussion with doctors to modify the attitude so that ADR reporting is considered as a duty toward society, (f) hold interdisciplinary discussion involving pharmacologist to increase knowledge about ADRs. Inclusion of pharmacovigilance related work in undergraduate and post graduate curriculum will go a long way in the success of PvPI.

Dentists also gave some important suggestion to improve ADR reporting like training and workshop on ADR reporting, availability of ADR forms at all departments and monthly case discussion on ADRs.
As this is single center study with limited numbers of dentists; the results of the study may not be generalized. A multicentric study may provide greater insight about underlying factors for under reporting of ADRs among dental professionals in India.

From various other studies and findings of the present study it appears that almost similar type of problems related with knowledge and attitudes are affecting the medical and dental practitioners. This needs to be addressed on urgent basis in order to improve spontaneous reporting and safety of the patients at large.

CONCLUSION

The present study suggests lack of knowledge and problem in attitudes of dental doctors as causative factors in under reporting of ADRs. These factors include lack of awareness about ADR reporting system, lack of risk perception of newly marketed drugs, inadequate training to recognize ADRs, fear factors, lethargy, lack of professional obligation, lack of risk perception of OTC and nonallopathic medicine and indifference. These factors should be considered while designing awareness programs and pharmacovigilance related workshops and training.

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