



A STUDY ON KNOWLEDGE, ATTITUDE AND PRACTICES OF PRIVATE DENTAL PRACTITIONERS REGARDING PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING IN JODHPUR CITY, INDIA

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ABSTRACT

Background: Most of the organized studies on assessment of knowledge, attitude and practices (KAP) regarding pharmacovigilance and Adverse Drug Reactions (ADRs) reporting have been done in medical field (not in dentistry), in hospital setups. Involvement of clinicians doing private practice was minimal. Thus, the present study was contemplated for private dental practitioners in Jodhpur to assess their knowledge, attitudes and practices regarding pharmacovigilance and ADR-reporting. **Methods:** A structured and validated questionnaire was used to obtain demographics of 116 private dental practitioners in Jodhpur, to assess their knowledge of pharmacovigilance, attitudes and practices regarding ADR-reporting, and factors that they perceived may influence reporting. **Results:** The knowledge and awareness about pharmacovigilance, amongst dentists was very low. About 70% respondents didn't know who could report. Only 23% had an idea what to report. Many dentists thought that ADRs due to ayurvedic and homeopathic (27%) and mouth washes and pastes (19%) should not be reported. Most alarming result was that although 61% dentists agreed that they had seen ADRs at their dental practice, none of the dentist in Jodhpur had ADR forms at their clinics (0%) and none had ever reported an adverse event to any national centers (0%). **Conclusion:** Our study strongly indicates the need to create awareness and to promote reporting of ADRs amongst dentists. The awareness about pharmacovigilance, amongst dentists was very low and almost none of the dentists have reported adverse drug reactions /events from their private clinics. The study was also a step to spread awareness and educate dentists about pharmacovigilance and ADR-reporting & to improve quality of patient care by ensuring safer use of drugs.

KEYWORDS: Adverse drugs reactions, Drugs, Dentist's Practice Pattern.

INTRODUCTION

Any substance that is capable of producing a therapeutic effect can also produce unwanted or adverse effects. Despite all the benefits of modern medicines, evidence continues to mount that adverse reactions to medicines are common, yet often preventable cause of illness, disability and even death. Apart from the intrinsic dangers associated with the products themselves, individual patients may exhibit particular and unpredictable sensitivities to certain medicines. In addition, if more than one medicine is prescribed, there is

always the risk of negative interactions. The selection and use of the best and safest medicine for a given individual out of many choices available thus requires considerable skill. Thus adverse drug reactions, skill related accidents/adverse events and medical emergencies represent an alarming problem that must be addressed by healthcare practitioners.

World Health Organization (WHO): defined Adverse drug reaction (ADR) as "any response to a drug which is noxious & unintended effects that occur at doses

normally used in man for prophylaxis, diagnosis or therapy of disease”.^[1]

An adverse event (AE) is defined as any untoward medical occurrence that results in death, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability and is life threatening.^[2]

The quality, safety and efficacy of drugs are very vital in public health. It has a direct impact on health of a population. One of the ways to achieve this is by putting in place an effective and efficient Pharmacovigilance system. WHO defined Pharmacovigilance as “science & activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine - related problems”.^[3]

Spontaneous ADR reporting is the cornerstone of pharmacovigilance. But disadvantage of this system is that there is a considerable degree of under-reporting. This might partly be explained by lack of knowledge and misconceptions about spontaneous reporting of ADRs. In order to improve the reporting rate, it is important to improve the knowledge, attitude and practices (KAP) of the healthcare professionals (HCP) regarding ADR reporting and Pharmacovigilance.

Most of organized studies on assessment of KAP has been done in medical field (not in dentistry) in hospital setups and in almost all studies the participants were medical doctors, post graduate students and nonteaching-faculty (junior doctors, pharmacist, nurses etc.).^[4,5,6] An important limitation in most of these surveys was that, involvement of clinicians doing private practice was minimal. Therefore, the present study was contemplated and done to assess the baseline knowledge, attitude and practices (KAP) of the dental professionals doing private practice in Jodhpur regarding ADRs and reporting. The study is also a step to spread awareness and educate dentists about pharmacovigilance and ADR reporting. We also aimed to get an insight into the reasons for non-reporting and to suggest appropriate measures of improving spontaneous reporting based on our findings.

MATERIAL AND METHODS

Study design: The ADR awareness program was a KAP study designed to obtain the demographics of the dentists and to assess the information about their knowledge of pharmacovigilance, attitudes and practices of ADR reporting, and the factors that they perceived may influence ADR reporting. In order to preclude any potential bias the disclosure of name of the responder was made optional.

Study frame: Names of private practicing dentists listed in IDA Jodhpur were obtained from Jodhpur IDA office. There were 60 dentists listed in IDA Jodhpur list. Further more, names of 63 dentists were acquired from yellow pages and BSNL directory. At time of study, out of 123

dentists, 7 were not available and so a total of 116 private dental practitioners were approached. A pilot study was undertaken on 10% of the study population (12 dentists).

Material: (1) A suitable piloted and validated self-administered survey questionnaire. (2) A power point presentation and its handout for educating dentist about pharmacovigilance. (3) Consent from all the dentists

Methodology: It was decided to administer the questionnaire and collect data from all the dentists who could be contacted in 3 visits. The questionnaire was handed to them after explaining them the purpose of the study. The doctors were requested to complete the questionnaire and hand it back immediately as it would be helpful to clarify doubts if any, about any question. Once the respondents handed over the filled questionnaire, they were educated about pharmacovigilance, ADR reporting, who, when what where and how to report. The hand out of the ppt shown to educate was distributed to them along with printout of few government provided ADR reporting form, to initiate and promote instant reporting by them.

Those who were busy at that moment were requested to keep the duly filled questionnaires at their receptions from where it would be collected within 1 day. Those who did not respond by next day (2nd visit), were requested again to fill the questionnaire and hand it back immediately, to maximize the response rate and were educated and given the handout and ADR reporting form.

The questionnaire was re-administered, if the reason of non-response was loss of the questionnaire. If the reason for non-response was busy schedule, the dentists were requested to suggest a suitable time when they would want to be contacted to return the filled questionnaire and for getting the awareness session. Such doctors were contacted at scheduled time (3rd visit) and if they were free, the questionnaire was collected from them and made aware about Pharmacovigilance and if they were not free/ busy, they were not contacted further.

Data analysis: From the data obtained by pilot study, reliability of questionnaire was assessed by using test-retest. The value of measured kappa (K) was 0.87 and weighted kappa (Kw) was 0.89. The internal consistency of the questionnaires was assessed by applying Chronbach's Alpha (α) and the value of $\alpha = 0.79$ was measured. The results of survey questionnaire were transferred to a master table and data was analyzed question wise and their percentage value was calculated and graphs were prepared.

RESULTS

A total of 116 dentists doing private practice in Jodhpur were contacted and given ADR awareness assessment questionnaire after briefing about purpose of study. Out

of 116 dentists approached, 112 answered the questionnaire, giving a response rate of 96.6%.

Our survey results revealed that knowledge and awareness about ADR reporting system, amongst dentists is very low. Although 96% of dentists thought they could report ADRs, they were not sure whether dental assistants, nurses, pharmacists or patient could report or not. Only 30% respondents knew who could report. Only 66% had an idea what to report. Rest of the parameters like when, how, where to report and confidentiality management are discussed in Graph 1.

Assessment of attitudes to ADR reporting in dentists showed that 96% dentists in our study believed that ADR reporting is necessary and 68% thought it is a professional obligation. Previous studies have also identified ADR reporting as a professional obligation.^[6,7] (Graph 2)

Although 71% respondents believed ADR reporting should be voluntary, 69% thought that voluntary system of reporting is main reason for under-reporting of ADRs and they thought ADR reporting should be made compulsory (Graph 2). In some countries for example Sweden, France, ADR reporting by healthcare professionals is compulsory, even though, the impact to counter underreporting is still controversial.^[8] Interestingly, a fee was not considered to be an incentive to report by 79% dentists. This issue has been addressed previously and it was concluded that the concept of having a sizeable fee might encourage reporting of trivial reactions while a small fee would not be a spur to reporting.^[9]

Out of 11 discouraging factors to report ADR, we found that reporting form not available at clinic (77%), not knowing where and how to report and even unawareness of the existence of a reporting scheme (88%), other colleagues not reporting ADR cases (52%) and fear of legal liability (58%) were the major factors which significantly influenced the ADR reporting among healthcare dentists (Graph 3). Reporting form not available was identified as a discouraging factor to report ADRs by other studies too.^[7,10]

On the other hand reasons which were not identified as significant to discourage ADR reporting among dentists included misconceptions about drugs being thoroughly researched before marketed, importance of single or minor/trivial ADR reports, time wasted in reporting and proficiency in identifying ADRs. Many dentists are reluctant to report minor reactions to newly marketed agents, perhaps because they do not perceive that the contribution this data can make to postmarketing surveillance is important. They believed that only safe drugs are marketed (30%) and that single reports won't affect ADR database (29%). Astonishingly 27% dentists considered dental ADRs to be too trivial an issue to report (Graph 3).

About 20% of dental practitioners were of opinion that reporting of ADRs takes too much time and 38% felt reporting will generate extra work at clinics. This might explain why even serious reactions are underreported. (Graph 3).

Some dentists thought that they might be wrong in identification of ADRs (39%). Similar result has been borne out from surveys of medical practitioners. Doctors were more likely to report if there was a degree of certainty that the drug had caused an ADR, despite the fact that almost all respondents knew that the CSM/MCA did not want to receive reports of only proven reactions. This is a consistent finding from all surveys, and may reflect the anxieties of reporters not to appear foolish', a sentiment that needs to be dispelled through communications from regulatory agencies and education.^[6] Indeed, a lack of clinical confidence in the diagnosis of an ADR is an important issue for practicing dentists also and their fear appearing to be incompetent or become subject of ridicule may cause them to report only ADRs that they consider certainly were caused by a drug.

Assessment of practices regarding ADR reporting divulged shocking data. An important finding was that only 5% dentists knew how to report ADRs and only 11% had an idea where to report. 59% respondents were not sure whether ADR monitoring centers maintain the confidentiality of doctors reporting ADRs or not.

Most alarming result in our study was that none of the dentist had ADR forms at their clinics (0%) and although 61% dentists agreed that they have seen patients experiencing ADRs/ AE at their dental practice, none had ever reported an adverse event to any of the national centers (0%). Only 1 out of 112 (<1%) respondents had attended a CME on ADR reporting as he had worked in WHO office for an year (Graph 4).

DISCUSSION

Adverse Drug Reactions (ADRs) are associated with a significant morbidity and mortality and it represents a substantial economic burden on healthcare resources.^[11,12,13,14] Recent estimates suggest 6.7% of hospital patients suffer 'serious' ADRs, 0.32% suffer fatal ADRs, and were thought to be between fourth and sixth leading cause of death in the USA in 1994. It caused one million deaths and 2.2 million hospitalizations.^[11] Incidence of ADRs is high despite the fact that drug research and monitoring centers endeavor to ensure that thoroughly researched and only safe drugs are marketed. It has been reported that 2.4-6.5% of total admissions in hospitals are due to adverse reactions, many of which are preventable.^[15,16] Incidence of serious ADRs is 6.7% in India.^[17]

The reason behind such high incidence of ADRs is that during developmental phase of a drug, a good deal is known about its therapeutic activity but rather less about

its safety because clinical trials are conducted in controlled environment on lesser number of patients/subjects. Once a drug gains entry into market, it will be prescribed by hundreds of doctors to thousands of patients belonging to different age groups. The scenario is complicated when there are ethnic variations, presence of co-morbid conditions and concomitant medications. During this phase only unusual and rare ADRs are encountered. So, if we have a system which can help us to determine any new information available in relation to their safety profile, it can be critically useful. Since there are considerable social and economic consequences of ADRs, there is need to engage healthcare professionals, in well structured program to build synergies for monitoring ADRs.^[5] This gave birth to branch of pharmacovigilance.

Voluntary ADR reporting schemes have operated since early sixties in many Western countries. These surveillance systems enable physicians and pharmacists to report suspected ADRs and thus act as a tool to identify new ADRs and risk factors predisposing to recognized ADRs.^[18]

The contribution of health professionals, in this regard, to ADRs databases is enormously significant and has encouraged ongoing ascertainment of the benefit-risk ratio of some drugs^[19,20] as well as contributed to signal detection of unsuspected and unusual ADRs previously undetected during the initial evaluation of a drug.^[21,22]

Spontaneous ADR reporting is cornerstone of pharmacovigilance and fundamental to medical drug safety surveillance. It has contributed significantly to successful pharmacovigilance. Though, this system is inexpensive and easy to operate and encompasses all drugs and patient populations, including special groups, substantial under-reporting and inability to calculate incidence of ADRs are inherent disadvantages of this system.^[17,23]

Our study indicated that awareness about ADR reporting system, amongst dentists is very low. Most alarming result in our study was the fact that none of the dentist had ADR forms at their clinics (0%) and none had ever reported an adverse event to any of the national centres (0%). An earlier attitudinal survey of ADR reporting in The Netherlands showed that the lack of availability of reporting forms and shortage of time were important reasons for non-reporting and some other studies have also shown similar under-reporting results.^[24,25]

In one of the studies, 72% of surgical specialists and 81% of medical specialists had diagnosed an ADR but did not report, due to multiple reasons. It is estimated that only 6-10% of all ADRs are reported.^[26] There is considerable degree of under-reporting, which might partly be explained by lack of knowledge and misconceptions about spontaneous reporting of ADRs. Our study showed that biggest factor which discouraged

ADR reporting by dentists was that they did not know how and where to report ADRs (99%). Similar observations are made in other studies as well.^[27]

It is obvious that lack of knowledge and awareness about pharmacovigilance, ADR reporting schemes and systems and reporting centers would automatically affect reporting. Results of our study and other similar studies reveal that management and propaganda of ADR monitoring is not perfect and needs serious rethinking.

The problem of underreporting is essentially due to absence of a vibrant ADR monitoring system and lack of reporting culture among health care workers. In order to improve reporting rate, it is important to improve KAP of the HCPs regarding ADR reporting and Pharmacovigilance. It can be done by awareness programmes and through publicity in practicing dentists and other HCPs. To improve spontaneous reporting rates, there should be continuous training programmes and an uncomplicated reporting system with quick feedback system. Studies have reported that gestures like acknowledgment of receipt of ADR report and an appreciation note would also help.^[4]

In present study, after filling questionnaire, during the discussion with respondents at time of ADR awareness session, all respondents agreed that the information about a system of ADRs reporting and monitoring was really valuable and that pharmacovigilance would be useful for them to be better healthcare professionals and also for their patients. They also said, regular continuing dental education/continuing medical education (CDE/CME) and workshops would be best means of improving ADR reporting.

Similar results from other studies have shown that doctors are willing to improve their knowledge of ADR reporting and increase their participation in pharmacovigilance program of the country proviso education and awareness on reporting scheme is instituted.^[5] Tabali M et al^[28] demonstrated that an educational intervention can increase physician awareness of ADRs, and that physicians were able to incorporate the knowledge they gained from face-to-face training into their everyday clinical practice. The effects of educational intervention, however, were temporary and hence regular retraining is essential.

In present study, although majority of responders had opined that awareness session about ADR reporting and monitoring system along with distribution of awareness handouts and ADR reporting forms had encouraged them to report further, but enthusiasm was probably lost due to lack of regular reinforcement and retraining sessions. A verbal feedback from all respondents was taken at end of one year and still none had reported an ADR in last one year. An email was sent to all respondent dentists to reinforce ADR awareness and promote reporting.

CONCLUSION

This study was first to initiate Pharmacovigilance programme in Jodhpur city of Rajasthan. Assessment of KAP regarding ADR reporting was done followed by an educational activity to provide importance of ADR awareness, reporting and training for better quality, safety and well-being of the future healthcare system.

The present study strongly suggests that there is a great need to create awareness and to promote the reporting of ADR amongst dentists. Training sessions to clarify the role of various healthcare professionals in pharmacovigilance, the events to be looked for and reported and to address the various perceived obstacles to spontaneous reporting, will hopefully fill the observed lacunae in knowledge and practices.

A closer relationship between doctors and pharmacovigilance centre and positive feedback of pharmacovigilance activities in hospitals are also suggested, as they are necessary for long term improvement of ADR reporting habits. Attitudinal and cultural changes, whereby ADR reporting become fully accepted and integrated into daily routines of doctors and is seen as an integral part of clinical activities and a duty, may take some more time and efforts.

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