



DENTAL PHARMACOVIGILANCE: EVALUATION OF INCIDENCE OF ADVERSE EVENTS, MEDICAL EMERGENCIES AND DRUG REACTIONS IN PRIVATE DENTAL CLINICS IN JODHPUR, INDIA

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ABSTRACT

Background: Depending on quality of training, Government of India has segregated type of treatment that can be performed by qualified dentists, trainees or nurses and who should prescribe what type of drugs, but these instructions are not being followed at dental clinics. Pharmacovigilance and reporting of Adverse-events (AE)/Adverse drug reactions (ADR)/Medical-emergencies (ME) has been one of the neglected areas in health care in India. The situation is even worse in dental practice. In order to promote skillful dental practice, rational use of drugs and adverse reaction reporting it is necessary to find out actual incidence of adversities happening in dental practice. **Methods:** A cross sectional observation study was conducted among all dental patients visiting various private dental setups at different locations of Jodhpur city, Rajasthan India for 1 year, to investigate incidence of AEs, MEs and ADRs. **Results:** In present study, a total of 14248 cases were observed. 1298 patients suffered some kind of adversity during treatment, giving the incidence rate of 9.11%. Successful, uneventful treatments were done for 12950(90.89%) cases. **Conclusion:** The present study provided valuable information to practitioners on incidence and pattern of AE/ME/ADRs in local population and was found to be useful to bring awareness & improve quality of patient care. **Practical implications:** This study was contemplated as an endeavor to assess AE/ME/ADRs during dental treatments and the information gathered is expected to aid in interventions that would improve quality of dental treatment and prescribing patterns.

KEYWORDS: Dental Pharmacovigilance, ADRs in dentistry. ADR incidence.

INTRODUCTION

The technological improvement, newer drugs, dental materials and urbane diagnostic tools for providing precise and quick diagnosis of oral diseases have all led to a tremendous improvement in dentistry.^[1] India has around 305 dental colleges, about 23,690 dental undergraduates and about 4000 dental post-graduates pass out every year from these colleges where around 12000 dentists work as staff.^[2]

This constitutes a vast number of oral healthcare professionals who are already practicing dentistry in society and those who would soon join the force every year. Hence we can expect large number of adverse events (AEs) that can happen in dental practice due to use of newer dental material or newer dental

technologies which require mastering before they can be practiced. Also there can be unfortunate events that can be classified as medical emergencies (MEs) in dental practice that require immediate management. The number of adverse events that can happen at dental clinics may increase due to Adverse Drug Reactions (ADRs). ADRs are considered to be important causes of illness and death in both ambulatory as well as hospitalized patients. The incidence of ADRs in hospitalized patients is about 10–20% and it is approximately 7% for the patients in the ambulatory setting.^[3] The rise in frequency of litigations against doctors and hospitals and increased patient awareness towards unpleasant effects of drugs/ events during treatment has made clinicians, hospital administrators

and health care planners aware of the necessity for closely monitoring AEs and ADRs.^[4]

Pharmacovigilance and Reporting of AE, ADR and ME has been one of the neglected areas in health care in India and no established reporting system at the National level has been completely active. The situation is even worse in dental practice. Government of India is still in process of establishing a successful and effective national pharmacovigilance program. The National reporting centres have been established but they are not functioning optimally.

Depending on quality of training, govt. of India has segregated the type of treatment that can be performed by qualified dentists, dental trainees or dental nurses and who should prescribe what type of drugs^[5] but these instructions are not being followed at dental care centres. Many authors have mentioned that chances of ADRs in dentistry are really low.^[6] These data suggest that greatest danger to patients is not a function of who is prescribing but from the content and quality of training one has received to learn how to treat/prescribe. In such situations, the need for finding out the actual incidence of adversities happening in dental practice and establishing a pharmacovigilance program in the country was felt by those who were interested in promoting rational use of drugs, adverse reaction reporting and skillful dental practice.

The present study was designed to find the incidence of AE/ME/ADRs which occur due to drugs, medicaments and materials used during dental treatment and during the treatment of pathologies in oral and maxillofacial region in private dental clinics in Jodhpur city of Rajasthan, India. Furthermore the study also intended to spread awareness and educate dentists about pharmacovigilance, ADR-reporting and also to encourage, coordinate, initiate and provide importance of attending consistent training programs on ADR reporting and Pharmacovigilance to dental professionals for better quality, safety and well-being of patients and future healthcare system.

MATERIALS AND METHODS

A cross sectional observation study was conducted among the dental patients visiting various private dental setups of Jodhpur city, Rajasthan, India to investigate incidence of AEs, MEs and ADRs. All patients visiting various private dental clinics during a period of 1 year were included. In total 14,248 patients visiting fourteen different private dental clinics formed the final study sample.

MATERIALS

Study Population: It comprised of all dental inpatients and outpatients visiting various private dental clinics of Jodhpur city for any treatment during a period of one year. All reactions/undesirable-events/conditions arising due to any material used for dental treatment, due to any

medicament/drug used in treatment for dental/head and neck lesions, due to any negligence/inadequate skill of dentist or dental assistant/nurse/trainee during treatment at clinic or due to accidental over dosage/negligence in following treatment plan by patient were included in the study. The AEs/ME/ADRs in patients with sadomasochistic habits, drug abuse or intentional poisoning were excluded.

A multicentre study was planned among various private dental care centres in different locations in Jodhpur city. A comprehensive list of all dentists of Jodhpur city was obtained by combing data from the Indian Dental Association (Jodhpur Branch) List, yellow pages and BSNL Jodhpur Directory. A list of 123 dentists was obtained, out of which 7 were no longer practicing. All the remaining 116 dentists were requested to participate in study to find incidence of AE/ADRs by providing their clinical details for 1 year. Fourteen centres were selected randomly covering various areas in the city. Each centre was surveyed for a period of 1 year.

Sampling Tools

1. Adverse event reporting form: Government approved form was downloaded from the website <http://www.cdsc.nic.in/writereaddata/adr1.pdf>
2. Ethical committee clearance: Ethical clearance was obtained from the ethical committee of the Jodhpur Dental College General Hospital, Jodhpur, India.
3. Study group consent: Consent forms were prepared in simple English language for easy understanding and convenience of dentists and written informed voluntary consent was obtained from all the centres which agreed to provide their data on ADR, AE, ME incidence during the study period of one year.

Training of the recording dentists: Each dentist who had shown interest in ADR reporting study was educated about pharmacovigilance, ADR reporting, who, when, what, where and how to report by the use of a power point. Clear instructions were given to the examiner about recording data in ADR forms. A hand out of the PowerPoint shown to educate was distributed to them along with printout of few standard, government provided ADR-reporting form, to initiate and promote reporting by them. Furthermore, posters were displayed containing text "Please Report Adverse events" in the clinics along with notification forms. All patients, who were suspected or reported for any possible AE/ME/ADR related problems, were recorded. All these patients were then closely monitored by the dentist, if they were prone to any other ADRs prescribed during treatment. The ADR forms were filled by the treating dentist and data was collected every week from the participant clinical centres.

Schedule of the study: The study was scheduled systematically to spread over a period of 2.5 years from January 2013-October 2015. A detailed monthly/quarter-yearly schedule was prepared well in advance by

informing and obtaining consent from respective authorities. Even though a detailed schedule plan was prepared well in advance, some adjustments had to be made while working it out practically. The data about patients from various private dental care centres was collected for a period of one year from January 2014 to December 2014.

METHODOLOGY

Study Sample: The sample size for estimating the incidence of AE, ADR and ME that occur among dental patients in private dental setups of Jodhpur City, Rajasthan, India, was estimated on the basis of following assumptions: (1) The margin of error (d): 1%, (2) Confidence level (α):99%, (3) Hypothesized % frequency of outcome factor in the population (p): 27%+/-1, (4) Population size for finite population correction factor or fpc (N):36,87,165. (Jodhpur census 2011)The final sample was estimated to be **13,031**.

Statistical procedures: The data obtained from dentists was compiled systematically. The data was transferred to a computer to prepare a master table using Microsoft Excel 2007. The Statistical software SPSS 16.0 was utilized for analyzing the data. Microsoft office Word and Excel 2007 have been used to generate graphs, tables etc.

For analyzing data for incidence study **Chi-square with Yates correction** was used for comparing various proportions. The **p-value (level of significance)** is a function of the observed sample results that is used for testing a statistical hypothesis. The level of significance in the present study was set at 0.05 (5%) (i.e. if p-value is ≤ 0.05 , result is Significant (S) but if p-value is >0.05 , result is Not Significant (NS))

RESULTS

In present study, a total of 14248 cases (6142 males and 8106 females) were observed during one year period at various private dental care centres at different locations of Jodhpur city. During the period of study, 1298 patients (584 males and 714 females) suffered some kind of adversity during treatment in private dental clinics, giving the incidence rate of 9.11%. These unexpected events were grouped into three categories –ADR, AE and ME. Successful, uneventful treatments were done for 12950 (90.89%) cases.

Surprisingly, incidence rate of ADRs showed that they were rare in dentistry and accounted for only 0.1% (14 patients out of 14248) of all cases included in study. The maximum incidence was that of AEs (physical and chemical injuries) and they alone accounted for 8.66% cases (1234 patients). MEs were also few and their incidence rate was 0.35% (50 patients) of all cases seen (Table 1; Graph 1). The proportion of AE, ME ADR, of all the adversities reported (n=1298) was found to be 95.07%, 3.85% and 1.08% respectively. (Graph 2)

Adverse events: The AEs, were grouped into 4 classes i.e. those arising due to prosthetic, restorative, surgical procedures or due to any other routine dental procedures (Table 2). Most of the AEs reported had occurred during restorative and surgical procedures. Together they accounted for about 61.51% of the entire AEs that had occurred in study sample. Orthodontic procedures and routine dental procedures like scaling, bleaching etc were quite safe and had been the reason for only 14.51% of all AEs the reported. The proportion (%) of AEs reported according to different types of treatment during which they had occurred is shown in Graph 3.

The gender distribution of all AEs reported was similar to the results of gender distribution of overall ADR/AE/ME reported. There was definite predominance of females in incidence of AEs. It was found that only 46.11% of AEs had happened in male patients while 53.89% of AEs had occurred in female patients of study sample. This difference was not found to be statistically significant. The most probable rationale for this can be that possibly more number of female patients seek dental treatment and any genetic or scientific basis cannot be attributed to such a ratio.

Adverse drug reactions: A total of 14 ADRs were documented in 1 year of time from various private dental care centres in different locations of Jodhpur city of Rajasthan, India. The most common ADR symptoms reported were giddiness, anxiety, gastritis, acidity, excessive diarrhea, dermatitis, swollen hands, edema, mouth ulcers, mouth erosion, erosive gingivitis, anti bioma formation and Steven-Johnson syndrome.

The medicines/dental materials which had caused these ADRs were categorized according to class of drugs and number of cases reported due to each was tabulated (Table 3). The ADRs in dental practice were reported rare (0.1% of all cases) and as in the overall gender distribution, ADRs also revealed a greater female predilection. 9 out of the 14 cases reported (64.29%) had occurred in females while only 5 cases (35.71%) occurred in males.

Medical emergencies: Only 50 MEs were reported during the study. The number and percentage of MEs reported were tabulated (Table 4). Syncope was found to be the most commonly occurring ME in clinical dental practice. (Graph 4) The gender ratios of patients who suffered syncope in private dental care centres during period of study was similar to that of overall MEs, showing a female predominance.

The female patients had dominated male patients in both ADRs and MEs. Although this data was not found to be statistically significant, the justification might be due to difference in physiology, sensitivity and other parameters.

Table 1: Number, percentage and gender distribution of ADR/AE/ME reported among the sample dental patients.

Condition	Males (N=6142) n (%)	Females (N=8106) n (%)	Total (N=14248) n (%)	Chi square (χ^2) test	Conclusion
Adverse events (AE)	569 (9.26)	665 (8.20)	1234 (8.66)	$\chi^2=4.883, df=1, p=0.028.$	S
Adverse drug reactions (ADR)	5 (0.08)	9 (0.11)	14 (0.1)	$\chi^2=0.083, df=1, p=0.773.$	NS
Medical emergencies (ME)	11 (0.18)	39 (0.48)	50 (0.35)	$\chi^2=8.272, df=1, p=0.004.$	S
Total AE/ADR/ME	585 (9.53)	713 (8.80)	1298 (9.11)	$\chi^2=2.153, df=1, p=0.142.$	NS

χ^2 = Chi-square value (Chi-square with Yate's correction, two tailed), df = degree of freedom, p = level of significance set at ≤ 0.05 , NS = not significant, S = significant.

Table 2: Number, percentage, gender and treatment wise distribution of adverse events (AE) reported in the study sample.

Condition : AE	Males (N=569) n (%)	Females (N=665) n (%)	Total (N=1234) n (%)	Chi square (χ^2) test	Conclusion
AE due to prosthetic treatment	123 (21.62)	173 (26.01)	296 (23.98)	Yate's $\chi^2=3.027, df=3, p=0.387.$	NS
AE due to restorative treatment	176 (30.93)	199 (29.92)	375 (30.38)		
AE due to surgical treatment	183 (32.16)	201 (30.22)	384 (31.11)		
AE due to other treat.	87 (15.28)	92 (13.83)	179 (14.50)		

χ^2 = Chi-square value (Chi-square with Yate's correction, two tailed), df = degree of freedom, p = level of significance set at ≤ 0.05 , NS = not significant, S = significant.

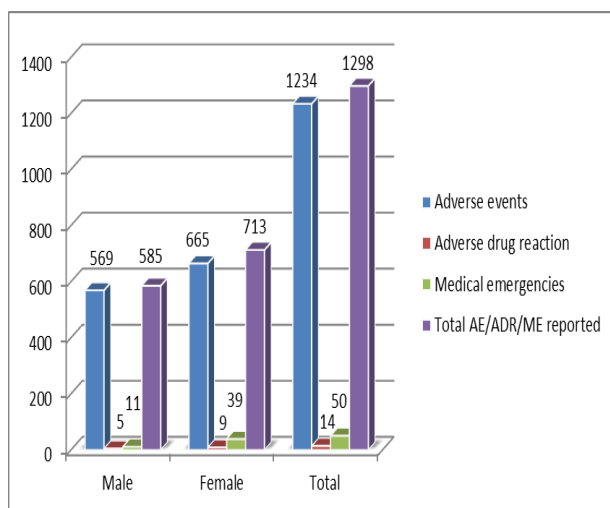
Table 3: Drugs associated with the ADRs reported in the study sample.

Sr. no	Name of drug	No. of cases	Class of drug
1	Ibuprofen	1	Anti-inflammatory & Analgesic
2	Ketorol-DT	2	„
3	Esgipyrin	1	„
4	Paracetamol	1	Antipyretic
5	Amclad 625	1	Antimicrobial
6	Amoxiclav	1	„
7	Amoxicilin	1	„
8	Moxikind-CV	1	„
9	Ordent	1	„
10	Sensodyne	1	Anti-sensitivity Paste
11	Sensofoam	1	„
12	Meswak	1	Routine Dental Paste
13	Amalgum	1	Dental filling material

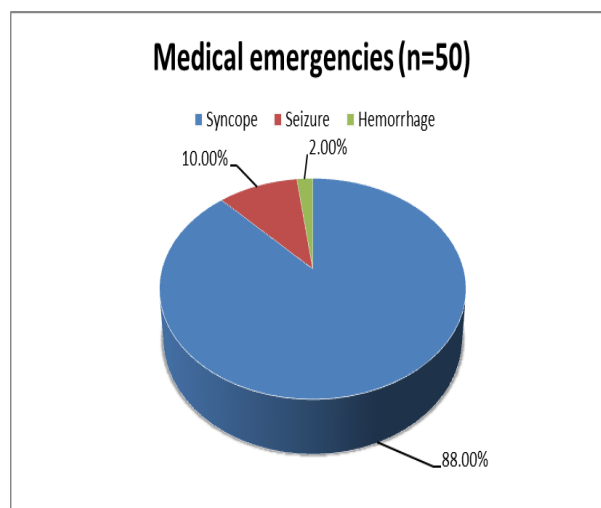
Table 4: Number, percentage, gender and types of Medical emergencies (ME) reported in the study sample.

Condition : ME	Males (n=11) n (%)	Females (n=39) n (%)	Total (n=50) n (%)	Chi square (χ^2) test	Conclusion
Syncope	8 (72.73)	36 (92.32)	44 (88.0)	Yate's $\chi^2=2.926, df=2, p=0.231.$	NS
Seizure/ Convulsions	3 (27.27)	2 (5.12)	5 (10.0)		
Hemorrhage	0 (0.00)	1 (2.56)	1 (2.0)		
Any other (hyperventilation, Anaphylaxis etc.)	0	0	0		

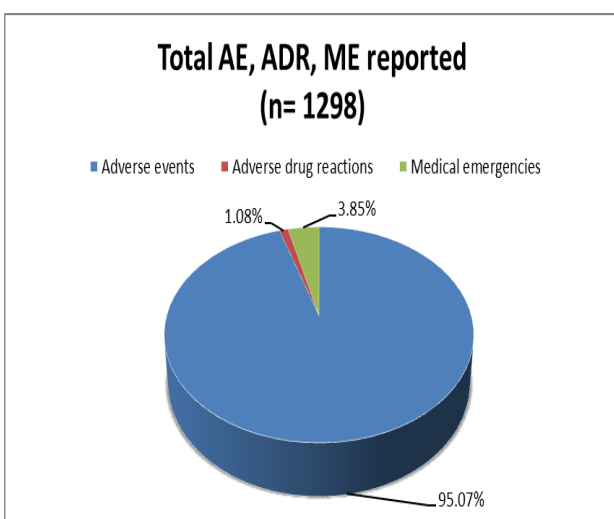
χ^2 = Chi-square value (Chi-square with Yate's correction, two tailed), df = degree of freedom, p = level of significance set at ≤ 0.05 , NS = not significant, S = significant.



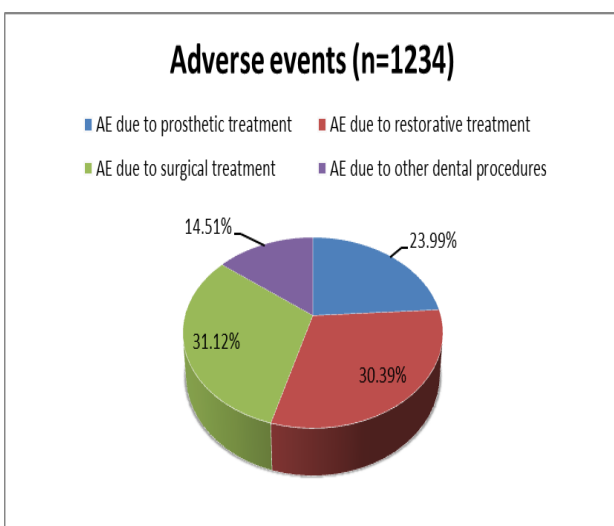
Graph 1: Total number AE/ADR/ME reported and their distribution in males and females in the study sample.



Graph 4: Proportion (%) of ME reported according to different types in the study sample.



Graph 2: Total proportion of AE, ADR, ME reported in the study sample.



Graph 3: Proportion (%) of AE reported according to different treatments.

DISCUSSION

Medicines play a vital role in disease prevention health care systems and in a developing country like India, making available good quality and affordable drugs along with the practice of rational prescribing is the need of the hour. A meticulous review of existing literature showed that the problem of irrationality in prescribing drugs is widespread in developing countries because of their experimental approach compounded by patient's economic constraints.^[7]

The problem of adverse drug reactions is the outcome of a variety of factors e.g., availability of numerous drug options to the doctors, incapability of any doctor to be proficiently informed on all aspects of all new drugs, the pressure by pharmaceutical companies to create a demand for any drug, canvassing by retail men, colleagues and even the persuasion of patients themselves to use a new drugs (which have been well advertised) on them, much before complete information about the human toxicity of the drug have come to be known.^[8]

A comprehensive continuous ADR monitoring program in a hospital can complement organizational risk management activities, evaluate safety of drug therapies, measure AE/ ADR/ ME incidence rates and educate those involved in health care about drug effects and increase their awareness regarding ADRs. Furthermore it is essential to periodically evaluate ADR data for analyzing incidence and pattern. Propagation of this information to the medical professionals helps in promoting drug safety in healthcare system. The ADR reports may bring about changes in the marketing authorization, for example, refinement of instructions of use, introduction of warnings of specific adverse reactions in product package insert or even restrictions in use. Rarely when a hazard is considered unacceptable, a medication may have to be withdrawn from the market.^[9]

Studies on incidence of ADRs, AEs in dental practice and MEs due to drugs and materials used in dentistry (filling materials, cements etc) are rarely been carried out. A limitation of most of the ADR monitoring surveys done on medical doctors was that the involvement of private practicing clinicians, pharmacist and nurses was minimal.^[10] This study was contemplated as an endeavor to assess AE and ADR during dental treatments in private dental health care centres. The information gathered is expected to aid in interventions that would improve quality of dental treatment, prescribing patterns, identification of medicaments used in dentistry with potential for ADR leading to their judicious and rational use in dental treatment. The present study was first to initiate an ADR awareness program promoting the AE/ADR/ME monitoring and reporting to find the actual incidence of AE/ADRs/ME in private dental care centres in Jodhpur city of Rajasthan, India.

ADRs are related with significant morbidity and mortality and they impose a substantial economic burden on healthcare resources.^[11-14] It caused one million deaths and 2.2 million hospitalizations.^[11,15] It has been reported that about 2.4-6.5% of total admissions in hospitals are due to adverse events/reactions and many of them are preventable.^[16,17] The incidence of serious ADRs in India is 6.7%.^[18]

In regard to ADRs databases, the contribution of health professionals is enormously significant and has led to establishment of the benefit-risk ratio of some drugs, and has also contributed to detection of signal of unusual and unsuspected ADRs which were previously unnoticed during initial evaluation of drug.^[19,20] Spontaneous ADR reporting is the cornerstone of pharmacovigilance and it is fundamental to drug safety surveillance. The Uppsala Monitoring centre (UMC, WHO), Sweden preserves the international database of ADR reports (currently about 4.7 million case reports) received from different international centres (96 member countries).^[21] Although, India is participating in the program, its contribution to UMC database is negligible and only a small percentage of ADRs are actually reported to pharmaceutical companies and ADR reporting centres nationwide.

In the present study, the adversities that happen in private dental practice, it was found that out of 14248 cases seen during one year of time at fourteen selected private dental care centres, situated at different locations in Jodhpur city, which participated in the study, a total of 1298 patients had suffered some kind of adversity (AE/ADRs/ME) during the treatments, giving an incidence rate of 9.11% in total. The results in addition, suggested that the female population had experienced higher incidence of AEs, ADRs and MEs. The maximum incidence was that of AEs (physical and chemical injuries) and they alone accounted for 8.66%, followed by MEs - 0.35% and then ADRs - 0.1% of all cases(14248) included in study. Our results showed that

ADRs were very rare in dental practice. Moore et al had mentioned that chances of ADRs in dentistry are really low because the dentists need to prescribe only a few groups of drugs and they perform it safely and with high standards.^[6]

Specific training recommendations can easily be done to significantly reduce the events. Practice can make one perfect but prescribing proper medications and performing successful, uneventful dental treatment requires skills that must start with early training. As in many professions, there are those who may lack the skills needed to correctly and competently perform tasks. Training that addresses AE and ADRs is not included/prominent in the core subject matter of the majority of dental schools. While this type of training may not guarantee the competence, without specific training, we may be inviting more AE and ADRs and their subsequent consequences.^[22]

CONCLUSION

The present study was found to be useful and provided valuable information to practitioners on the incidence and pattern of AE/ME/ADRs in the local population. This type of program can bring awareness for healthcare professionals & improve the quality of patient care. Monitoring of adverse events and drug reactions is an ongoing ceaseless and continuing process, in which all health care professionals and pharmacists play a vital role to enhance effective patient care.

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