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Review Article

Review On Pharmacovigilance In Dentistry

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ABSTRACT

Pharmacovigilance is a term of pharmacology which helps in the observation, evaluation, understanding, and prevention of long-acting and short-acting adverse effect of various medicines.¹ Dental pharmacovigilance has evolved to the point that dentists must keep up to speed on new pharmaceuticals, drug safety, and treatment trends on a regular basis. The safe use of drugs in dentistry is critical for patient's well-being. The dental discipline is involved in the use of a variety of drugs in the treatment of oral diseases. Dentists are aware of drugs side effects but they should be aware of adverse drug reactions of other drugs. so, this Dental pharmacovigilance is a new important trend for dentist in treating patient with oral disease.²

INTRODUCTION

WHO defines Pharmacovigilance as, it is the science and activities relating to the detection, assessment, understanding and

prevention of adverse effects or any other drug related problem.³ It mainly gives emphasis on adverse drug reactions to a drug which is harmful and unintended including lack of efficacy used for

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the prophylaxis, analysis or therapy of illness or for the modification of physiological function. 4

HISTORY OF PHARMACOVIGILANCE

The US Federal Food and Drug Act were formed on June 30, 1906, and it established that drugs must be pure and free of any contamination. Furthermore, in 1911, this organization forbade false therapeutic indications of drugs. Later in USA (1962), the amendment, requiring safety and efficacy data of drugs before premarketing submission, was approved while in 1964, the “Yellow card” (YC) was structured in the UK, which was a specific form to compile a spontaneous report of drug toxicity. In 1992, the European Society of Pharmacovigilance (ESoP) was supported, turned into the International Society of Pharmacovigilance (IsoP) with the aim to promote Pharmacovigilance, and enhance all aspects of the safe and proper use of medicines. In 1995, the European Medicines Agency (EMA) was formed. In 2001, EudraVigilance was supported . It is the official European database for managing and analyzing information on suspected adverse reactions to medicines which have been authorized for the market or being studied in European clinical trials.5

HISTORY OF PHARMACOVIGILANCE IN INDIA

Pharmacovigilance in India started from 1986. A formal Adverse Drug Reactions monitoring system was initiated with 12 regional centres, each covering a population of 50 million. In year 2005 WHO supported and World Bank funded National Pharmacovigilance Programme of India was made operational.5

PHARMACOVIGILANCE IN DENTISTRY

ADRs in the field of dentistry can cause a wide range of oral manifestations involving both hard and soft tissues. These reactions can occur as a result of using various drugs during dental procedures or as side effects or reactions of systemic medications . Regarding the

manifestations of oral soft tissues, ADRs can take different forms depending on the type of drug involved. Some patients may experience tissue swelling, resulting in gum enlargement, when taking drugs such as anticonvulsants, calcium channel blockers, or immunomodulators . Others may develop swelling of the oral mucosa, involving the lips, tongue, and rarely the uvula , following the use of drugs like ACE inhibitors, local anesthetics, and antibiotics . The other common manifestations of ADRs include oral candidiasis, a fungal infection characterized by white and red patches or lesions on the oral mucosa, which can be favored using antibiotics, corticosteroids, or immunomodulators . Additionally, cheilitis, the inflammation of the lips, presenting with redness, burning, and fissures, can occur following the use of various drugs such as ACE inhibitors, local anesthetics, aspirin, and others . ADRs can also cause erythema multiforme, a mucocutaneous condition that leads to red, swollen, and vesicular lesions that can involve the entire oral mucosa. Antibiotics, anticonvulsants, antiretrovirals, and non-steroidal anti-inflammatory drugs (NSAIDs) are some of the medications that can cause this condition . Another possible lesion is fixed drug eruption, which is characterized by the recurrence of a rash or lesion in the same location each time the drug is taken. 6 The other ADRs involving soft tissues include lupus-like lesions, presenting as skin rashes or ulcers that can appear in the oral cavity following the use of drugs such as beta-blockers, anticonvulsants, chlorpromazine, isoniazid, and others. Contact oral lesions occur when the oral mucosa comes into contact with an irritating or allergenic substance present in certain medications, such as aspirin, trichloroacetic acid, potassium tablets, and others, causing inflammation, redness, swelling, and ulcers in the contact area . Superficial and transient mucosal pigmentations can be caused by medications such



as amiodarone, antibiotics, chlorhexidine, and others. ADRs can also affect the salivary glands, causing hyposalivation (reduced saliva flow), leading to a dry mouth, or they can cause secondary Sjogren's syndrome due to medications such as PD-1 immune checkpoint inhibitors . Conversely, some patients may develop excessive salivation (sialorrhea), resulting in increased saliva or difficulty swallowing due to medications such as antipsychotics, general anesthetics, anticholinesterases, anxiolytics, anticonvulsants, and others . Regarding the manifestations in hard tissues, ADRs can impact the dental elements and the underlying bone. Intrinsic and extrinsic dental pigmentation, which are characterized by tooth discoloration, can be a side effect of certain medications, such as antibiotics, chlorhexidine, and fluoride supplements. Drug-induced bruxism, which refers to the involuntary grinding or clenching of teeth, can be triggered by medications such as anxiolytics, antidepressants, antipsychotics, and other drugs that affect serotonin and noradrenaline reuptake . Lastly, jawbones can also be affected by ADRs due to the onset of osteonecrosis. The medication-related osteonecrosis of the jaw (MRONJ) is often associated with the use of drugs such as antiresorptive and antiangiogenic agents. Safe use of Drug in dentistry is an important aspect in patients life. In day to day practice usually dentists are familiar with adverse drug reactions caused by drugs that they prescribe for treatment of mucosal conditions, still dentists also need to be aware of the other drugs that can cause oral reactions that require dental involvement.⁸ The wider range of therapeutic options from different group of drugs makes dental practitioners to provide therapeutic interventions that previously were not possible.⁹ Dentists are responsible for understanding the common advantages and adverse effects of available drug choices and must dentist should self report any unexpected side effects from those drug

treatments. Drug safety depends mainly on the monitoring of medicines once they have been marketed and prescribed. In order to make drugs more safe and effective in dental procedures, it is important to advise a culture of safe drug usage and immediate reporting to avoid major drug disasters. ¹⁰Post marketing adverse drug reactions reporting is important because tests in animals are insufficient to predict human safety, because clinical trials use a selective and limited number of patients for a short duration with different conditions than those involved in clinical dental practice. Information about rare but serious adverse reactions, chronic toxicity of drugs, use of certain drugs in special groups such as children, pregnant women, or the elderly, or drug interactions often is incomplete or not reported. Clinical trials may be a better method to check drug's efficacy than its safety during day to day clinical usage. The basic component of the pharmacovigilance process in dentistry starts with adverse-event data generation from patients. Data collected through various methods from patients should be evaluated by manufactures for seriousness, expectedness, and causality.¹¹

CONCLUSION

While major advancements in the discipline of pharmacovigilance have taken place in the West, not much has been achieved in India. However, with more clinical trials and clinical research activity being conducted in India, India's pharmaceutical industry is now the third largest in the world in terms of volume, 14th in terms of value and now emerging as an important clinical trial hub in the world still there is a massive need to understand and implement pharmacovigilance. ¹²Developments in dental pharmacotherapeutics require dentists to constantly update their knowledge of new drugs, drug safety, and therapeutic trends. Dentists must acknowledge the reporting benefits the practice of adverse drug reaction in dentistry as a whole. Early and more



proper documentation of adverse drug reaction will directly influence the speed with which problematic drugs can be withdrawn from the market, directly affecting the lives of patients and more safety will be achieved by the dental fraternity as well. The pharmacovigilance clinical practice in dentistry contributes to the establishment of greater therapeutic safety, helps to prescribe rationally and to make adequate decisions. The prescribing and usage of medications for dentist could damage health and environmental as a medical care. Focused on good dental practices, treating humans and the environment as a single, integral patient, the incidence of drug related problems and environmental damage could be reduced. The faculty of dentistry is committed and conscientious to the university community with the correct procedure of elimination of pharmaceuticals, medicines and dental materials, contributing with its contribution to the creation and maintenance of sustainable cities.1

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Table 1 : Drugs Commonly Used In Dentistry And Their Adverse Effects

ADVERSE EFFECTS	NAME OF THE DRUG
Altered taste	Allopurinol, clarithromycin, enalapril, ethambutol, griseofulvin, imipenem, phenytoin, selegiline, tetracyclines, venlafaxine
Angioedema	ACE inhibitors, aspirin, captopril, cephalosporins, indomethacin, penicillamine, quinine, streptomycin
Chelitis	Atorvastatin, isoniazid, methyldopa, streptomycin, tetracyclines, vitamin A
Erythema multiform	Allopurinol, amlodipine, carbamazepine, co-trimoxazole, ethambutol, fluconazole, furosemide, phenytoin, rifampicin, tetracyclines, valproate, vancomycin
Gingival swelling	Amlodipine, cyclosporine, diltiazem, oral contraceptives, phenytoin, Valproate
Hyper salivation	Amiodarone, clonazepam, gentamicin, lamotrigine, Nicardipine, venlafaxine,
Oral candidiasis	Corticosteroids, broad spectrum antimicrobials, immunosuppressives
Oral mucosal pigmentation	Arsenic, bismuth, busulphan, carbamazepine, chloroquine, cyclophosphamide, gold, iron, methyldopa, oral contraceptives, zidovudine
Oral ulceration	Alendronate, allopurinol, captopril, diclofenac, gold, indomethacin,osartan, naproxen, olanzapine, phenytoin, sulindac, vancomycin
Orofacial pain	Biperidin, griseofulvin, lithium, penicillins, vitamin A
Parasthesia	Amitryptiline, hydralazine, interferon alpha, isoniazid, mefloquine, nitrofurantoin, phenytoin, streptomycin, vincristine
Salivary gland pain / swelling	Clonidine, Insulin, naproxen, phenytoin
Tooth Discoloration	ACE inhibitors, doxycyline, penicillins