Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 6, 2021, Pages. 10543 - 10546
Received 25 April 2021; Accepted 08 May 2021.

Need for Implementation of Pharmacovigilance in Dental Care in India

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Abstract:

The medications which are used for preventing or curing different types of diseases have some risks associated with it. The medications are being prescribed by assessing their risk-benefit ratio. For the purpose of causality assessment, many tools have been developed which ranges from simple to other types of evaluating tools which demands more complex assessment. The causality assessment is an important tool in pharmacovigilance as it helps in determining the probability of ADR and the medications which commonly cause adverse drug reactions. Common disorders where ADRs have been reported are dermatologic, psychiatric, followed by central nervous system and gastrointestinal disorders. Most drugs have ingredients which can pose potential and unpredictable harm; this is especially so with availability of widening range of pharmaceutical drugs with varied potency. To integrate pharmacovigilance into routine clinical practice and in various health tier, much more is required. In this digital age, increasing use of the Internet has resulted in a change in access to all pharmaceutical products and information on them, giving rise to need of more vigilant safety measures. Under-reporting affects both old and new drugs and both serious and non-serious drug reactions. Hence the need for strict compliance of pharmacovigilance in dentistry is necessary.

Keywords: Pharmacovigilance, Adverse drug reaction, dental care.

Introduction

A drug is “any substance or product that is intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipient.” (WHO) Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, and prevention of adverse effects or any other drug-related problem.” (WHO) The medications which are used for preventing or curing different types of diseases have some risks associated with it. The medications are being prescribed by assessing their risk-benefit ratio. WHO established the program for International Drug Monitoring after the Thalidomide disaster happened in 1961. The pharmacovigilance tries to improve the patient safety and also aid in choosing the right medication according to their risk-benefit ratio.[1]

Medications are drugs that are used for diagnosing curing, or treating a disease. The drug therapy is an inevitable part of the medical field. There are different classes of drugs that are classified based on their component, pharmacological action etc. Antipyretics, analgesics, antibiotics, antiseptics, hormone replacement, etc. are only some among the drugs which are used commonly. Medications are being widely prescribed for different conditions. The selection of a particular medicine is based on their risk-benefit ratio. Most of the drugs which are used commonly have some adverse drug reactions. The adverse drug reactions range from simple frequent symptoms such as nausea or headache to severe effects such as anaphylaxis, hepatotoxicity, organ failure, etc.[2,3]

An adverse drug reaction (ADR) can be defined as “any harmful or unpleasant effect caused by taking a medication at doses intended for therapeutic effect.” WHO defines ADR as “any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function”. As adverse drug reactions are common when taking drugs, a health care worker needs to know the frequency and the risks which are associated with use of the drugs along with the benefits. ADRs are considered as a leading cause of morbidity and mortality. ADRs can be mainly categorized into two, one is the augmentation of the known pharmacological action of the drugs and is common. The other category represents the idiosyncratic reactions that are unpredictable. Pharmacological reactions depend on the drug dose, the pharmaceutical formulation, drug interactions, etc. Idiosyncratic reactions are not usually dose-dependent and they occur due to drug interactions, receptor abnormalities, etc. It can be multifactorial, affects organ systems, and can be fatal.[1,4,5]

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Association between exposure to a drug and the subsequent occurrence of ADR can be evaluated using causality assessment. The causality assessment is an important tool in pharmacovigilance as it helps in determining the probability of ADR and the medications which commonly cause adverse drug reactions. As pharmacovigilance heavily focuses on the adverse drug reactions, the causality assessment tool is very helpful to fulfil the goals of pharmacovigilance. Causality terms include conditional, certain, likely, possible, unlikely, probable etc. To reduce discord between assessing persons and to meet the escalating demand for causality assessment, many tools and executable designs were developed to have an organised approach (e.g. decision tables, pattern detection).[4]

Assessment of Adverse Drug Reaction

The assessment of ADR's requires a structure for achieving uniform agreement among evaluators irrespective of their difference in clinical background and expertise. For the purpose of causality assessment, many tools have been developed which ranges from simple to other types of evaluating tools which demands more complex assessment.

The assessment tools are an important aid in pharmacovigilance as they limit the disagreement between the different assessors and also to get an idea about the specificity of medication which is responsible for the particular adverse drug reaction. Numerous methods are available for establishing the causal relationship between the drug and the adverse drug reactions. They include clinical judgment and global introspection, algorithms, probabilistic methods, etc. Some of these methods include the Swedish method, WHO-UMC scale, Naranjo algorithm, Kramer algorithm, Karch algorithm, Begaud's algorithm, Bayesian adverse drug reaction diagnostic instrument etc. None of these methods are universally accepted and a gold standard is not established yet. As none of the methods are considered as universally accepted, the clinicians will prefer the simple and user-friendly methods depending on the other study features.[5,6]

Although the drug monitoring systems are well established in some countries, they are not established widely in some other countries. The ADRs are an additional cost to the already burdened health care system and can be prevented to a certain extent by the implementation of the drug monitoring system widely. In most of the countries, ADR's are under-reported and undisclosed due to a lack of monitoring and priority. As the use of drugs increased widely, the proper drug monitoring and study of the incidence of adverse drug reactions are essential to control them and ensure patient's safety.[7,8]

Systems affected commonly

ADR reporting is spelled out as a practice of continuously monitoring the undesirable effects caused by using drugs. Pharmacovigilance plays an important role in monitoring the ADR's. Many studies are there for the study of adverse drug reactions in children. Children respond differently to drugs when compared with adults. This is due to the immaturity of the immune system and development. The off- label use of drugs and communication barriers between children and adults increases the ADR risk in paediatric patients. Common disorders where ADRs have been reported are dermatologic, psychiatric, followed by central nervous system and gastrointestinal disorders.Adverse drug reactions can also be observed in neonates exposed to medications in utero. Anticonvulsant hypersensitivity syndrome is found in children due to the use of drugs such as phenytoin, carbamazepine, etc.[9]

Several comparative studies were found for algorithmic methods. Even though there are numerous methods, none of them is universally accepted. From the studies, it is found that the algorithmic methods are mostly preferred by clinicians and researchers due to their simplicity. The Naranjo scale and WHO-UMC were found as the most commonly used algorithmic methods. There are some specific algorithmic methods accepted in some special cases. Most of the other causality assessment methods were found to have no specific advantages over others.[10]

Necessity in Dental practice

In an observational study conducted among dental students in Jodhpur, it was found that dental students had a favourable attitude towards pharmacovigilance. However, their knowledge and practices were found to be short of acceptable standards.[11]

As per the World Health Organization (WHO), pharmacovigilance is the “Science and activities relating to the detection, assessment, understanding and prevention of adverse effects (AEs) or any other possible drug-related problems”.[12] In India pharmacovigilance has not taken root due to following reasons: Inadequacies of the health care system to document and report adverse drug reactions, for want of necessary awareness about usage of drugs among people and delay in enforcing strict pharmacovigilance system by the concerned authorities.[13]

The results from a study conducted in Tamil Nadu revealed that majority of dental practitioners were of the view that ADRs reporting is important, however, 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. Irrespective of the experience, gender and qualification, the dentists were shown to have favourable attitude towards reporting of ADRs.[14]

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Most drugs have ingredients which can pose potential and unpredictable harm; this is especially so with availability of widening range of pharmaceutical drugs with varied potency. When it is prescribed by qualified health professionals and used by those who understand the consequences of consumption of drugs, the chance of having adverse effects is reduced. When an adverse effect of a drug appears unexpectedly, it is very much necessary to communicate it effectively to patients and their care takers, so that they could interpret the effects caused by the drug. Up to certain extent, this practice is in place. To integrate pharmacovigilance into routine clinical practice and in various health tier, much more is required.[15]

Lack of awareness about pharmacovigilance among medical, dental and nursing staff were reported in one of the studies conducted in North India. It was found that reporting of adverse effects was quiet low in spite of incidences of such occurrence in the health care centres. Majority of the staff were of the opinion that reporting of such adverse effects is necessary and there is lack of awareness about the reporting. Training in pharmacovigilance and reporting were considered essential by the subjects of the study.[16]

In this digital age, increasing use of the Internet has resulted in a change in access to all pharmaceutical products and information on them, giving rise to need of more vigilant safety measures. The introduction of e-commerce in the world, which provided convenience to consumers along with offers, discounts, and home-delivered products over the past decade, also led to the development of the cyber pharma drug market.

Internet facility is widely available in Europe. In this era of increased internet penetration even in remotest area in developing nations like India, varied pharmaceutical products are available with high risk of misinformation. Discounts, convenience to pay and home delivery are the factors which attracts consumers to buy pharmaceutical drugs online.[17] In order to achieve a robust pharmacovigilance system, collective effort from drug manufacturers, pharmacists, clinicians, policy makers and the general public is needed.[18] Contribution from patients will also add to the awareness about drug safety.[19]

Reporting of adverse drug reactions should be made voluntarily by health care professionals, but reporting is usually not done in many countries including developed nations and it is a stumbling block to surveillance of drug safety standards.[20] Under-reporting affects both old and new drugs and both serious and non-serious drug reactions. Media coverage gained and reporting rate can fluctuate over time. Under-reporting also leads to situation in which the adverse reactions between drugs cannot be compared.[21]

Drugs can also cause harm while being used with the intention to relieve the suffering. It can be offensive for the patients. Reports suggest that ADRs occur for 5% of all hospital admissions and in in-patients it occurs to 10-20%.[22]

Clinical pharmacists can aid in dentists in identifying adverse drug reactions. Clinical pharmacists' role in identification of adverse drug reactions is well understood and can put forth a joint effort in addressing the adverse drug reactions along with other health care professionals.[23]

The role of clinical pharmacists in reducing drug related problems in elderly cannot be underestimated. Interventions by clinical pharmacists' that were approved by physicians can significantly reduce drug related problems in geriatric population.[24] This can be followed in the field of clinical dentistry too.

Conclusion:

The current adherence topharmacovigilanceneeds further progress as was revealed from studies available. Dentists have to get themselves motivated and take initiative in following standard adverse drug reaction reporting system in both Government and private teaching institutions as well as in private dental practice in India.

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