Journal of
Clinical and Pharmaceutical Research
REVIEW ARTICLE OPEN ACCESS

A Review on Adverse Drug Reactions

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ARTICLE INFO

Article History:
Received: 18.08.2021
Revised: 27.09.2021
Accepted: 07.10.2021

Keywords :
Adverse Drug reactions
Pharmacovigilance
Polypharmacy

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ABSTRACT

Adverse Drug Reactions (ADRs) became as one of the global problems that affect both children and adults with varying intensities. A significant number of ADRs may occur in elderly due to the contribution of drug-drug interactions, who are under polypharmacy. Various definitions are available all over the world in case of ADRs. But the definition by the World health organization was well adopted and widely accepted by many countries across the world. To promote the identification and reporting of ADRs and also to ensure and enhance the patient safety certain measures has to be taken by all health care professionals. The contribution of health care professionals, in regard to ADRs database is very much important and has encouraged the ongoing certainty of benefit risk ratio of drugs and also contributed to detect the unusual ADRs which are undetected during the basic evaluation of the drug. Pharmacists have a vital role in the maintenance of drug safety by contributing towards the prevention, detection, documentation and reporting of ADRs. The hospital or clinical pharmacist should actively participate in the area of pharmacovigilence in order to strengthen the National pharmacovigilance program.

Introduction

Contemporarily, health complications have been controlled and brought benefits significantly by the contemporary treatments. Despite of all the benefits, on the other hand as a result of these treatments adverse drug reactions (ADRs) may occur which are sometimes preventable, cause illness, disability and even fatal. Recently, United States senate has passed a bill which describes the requirement of pharmaceutical companies to provide the information to the drug consumers about the ADRs. Due to this reason, ADRs had drawn a great public attention all over the world at present [1].

ADRs became as one of the global problems that affect both children and adults with varying intensities. A significant number of ADRs may occur in elderly due to the contribution of drug-drug interactions, who are under polypharmacy. The interest in ADRs got elevated due to the 1960s thalidomide disaster. In the early 1960s to evaluate the incidence of ADRs among hospitalized patients various prospective studies were carried out in which all the ADRs were reported by health care professionals. During the period 1966-1996, it has been found that the ADRs related to prescription and over the counter drugs were observed to be 6.7% and out of them 3.2% were found to be dead in United States. Some of the epidemiological studies showed that ADRs account for about 5% of all hospital admissions. When a patient is hospitalized, the risk of ADRs increases automatically [2].

Various definitions are available all over the world in case of ADRs. But the definition by the World health organization was well adopted and widely accepted by many countries across the world. According WHO an ADR can be defined as "any response to a drug which is noxious, unintended and occurs at doses used in man for prophylaxis, diagnosis or therapy". In simple words we can describe an ADR as an unwanted effect of a drug beyond its expected therapeutic effects occurring during its use [3].

To know the causal relationship between the drug and its effect causality assessment should be done by using standard methods. The Naranjo's scale is commonly used, simple and most popular scale among clinicians because it was well structured, transparent, consistent and easy for application. WHO scale is also a well structured scale for the causality assessment. During the evaluation of an ADR, the predisposing factors must be taken into the consideration and some ADRs may be associated with particular patient and or drug related factors. These factors include pharmacokinetic and pharmacodynamic profile of a drug which might be influenced by the pathological condition of a disease,

physiological status, life style and concomitant treatment [4].

Usually drugs are studied in a controlled environment for a relatively less number of patients and for a limited period of time, during clinical trials. The drug approval process includes extensive testing for safety and excludes the geriatrics, pediatrics and patients with comorbidic conditions. Once the drug is approved and commercially available special population who are excluded in the clinical trials are exposed to the medication and there might be a chance to identifying the undetected complications in the past. In addition to that, frequency of ADRs incidence which is undetected in small sample of population can be noticed once the drug is available in the market. It is estimated that 51% of serious ADRs of marketed drugs were not identified before the approval of the drugs. Pharmacovigilance which can also be acknowledged as post marketing surveillance mainly involves the process of detection, reporting and responding to risk benefit concerns exist with the marketed drugs. These reports are beneficial to update the labeling of drug and to reevaluate the drug approval. In addition, these reports are also beneficial to provide information about the potential complications due to the drugs and to provide guidelines for safe administration of the drugs [5].

At present voluntary reporting of ADRs by health care professionals are desirable to detect and manage the ADRs there by minimizing the unwanted effects. It is also considered as a significant contribution to the drugs and their safe use. National pharmacovigilance reporting centres can manage all the ADR reporting systems and these systems may vary from nation to nation. In United States, the FDA medical products reporting program – MEDWATCH is an approach, planned to educate all health care providers about the clinically significant ADRs, their monitoring and reporting to the FDA and the manufacturer. This will ensure the safety information of drugs which should be communicated among the medical community that enhances the patient care. The main objective of Med watch program is to increase the effectiveness of phase IV trails/ post marketing surveillance of drugs which are used in regular clinical practice and also to detect important harmful effects associated with drugs. To determine the safety profile of a drug FDA evaluates reports from various sources such as pre marketing studies, post marketing studies, case reports and observational studies. In United Kingdom, yellow card scheme helps as a cautionary system in detecting the severe and unpredictable ADRs [6].

In India, the central drugs standard control organization (CDSCO) in association with Ministry of health and family welfare started the national pharmacovigilance program in November 2004. The integrated set up of ADR monitoring centre at a regional or hospital level can provide information about unusual or rare ADRs which are more prevalent in Indian population.

Brewer proposed that spontaneous reporting remains the most efficient way to identify rare adverse effects that occur in relation to the time with the use of drug. All over the world, post marketing surveillance programs are necessary to monitor the ADR occurrence and the data generated can be utilized for the national regulatory decision making. The ADRs can have significant impact on health care costs of a nation. In India, due to extensive and unmonitored use of drugs there could be high risk of the occurrence of ADRs. The above mentioned programs can reduce morbidity, mortality, length of hospital stay health care cost and embarrassment due to ADRs [7].

Actually, it is tough to initiate the clinical diagnosis of a drug induced disease as ADRs may initiate a naturally occurring process of a disease. But few drugs produce distinct or particular considerable physical signs. Approximately 57% of the community acquired ADRs are not being identified by the clinicians during the hospital admission which results in improper management. The aspects include to identify and manage ADRs include careful observation and high clinical suspicion to detect a drug related problem and undetected ADRs for marketed products for better management of ADRs and increased patient safety.

Both the health care professionals and patients should feel as their responsibility to share about the determination of drug safety profile once the drug is available in the market. The health care professionals need to consider the drug therapy as well as the benefits and risks when making the therapeutic choice and they need to be aware of their role and responsibility in the identification, management, and documentation and reporting of ADRs and all the necessary activities for optimizing the patient safety. A

well organized ADR monitoring program should be implemented to detect ADRs which often be unrecognized or unreported, actively or consequently enhance the patients' quality of life [5,7].

To promote the identification and reporting of ADRs and also to ensure and enhance the patient safety certain measures has to be taken by all health care professionals. The contribution of health care professionals, in regard to ADRs database is very much important and has encouraged the ongoing certainty of benefit risk ratio of drugs and also contributed to detect the unusual ADRs which are undetected during the basic evaluation of the drug. Even though these are the benefits of spontaneous reporting, the underreporting remains as a major drawback. The tremendous rate of under reporting is the major cause in delaying the signal detection and consequently it has negative impact on community health. Inman has described the factors as "the seven deadly sins". His description of sins include attitudes relating to professional activities includes financial incentives (rewards for reporting); legal aspects etc and complications associated with ADR related knowledge & attitudes such as complacency, diffidence & indifference, ignorance etc; excuses done by professionals such as lethargy [8].

Conclusion

Pharmacists have a vital role in the maintenance of drug safety by contributing towards the prevention, detection, documentation and reporting of ADRs. The hospital or clinical pharmacist should actively participate in the area of pharmacovigilence in order to strengthen the National pharmacovigilance program.

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