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Pharmacovigilance As An Important Tool For Reducing Adverse Drug Reactions.

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ABSTRACT

Before a drug being marketed or made available to the patient clinical trials of the drugs is carried out to check its safety and efficacy, whether it produces any adverse event or serious adverse drug reactions (SADRs), how well the drug works, it's benefit-harmful profile, Is it producing more harmful effect than benefits, by the manufacturer and If a drug passes the clinical trials it can be marketed.

Despite these clinical trials various unexpected and serious adverse drug reactions (SADRs) repeatedly occur after marketing. This study of adverse drug reactions (ADRs) is pharmacovigilance.

Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects particularly long term and short-term side effects of medicines8.

The pharmacovigilance aim is to provide the benefit, effectiveness, safety, harm, risks of medicines on patients, as well as safeguard the rights, safety and wellbeing of all patients in relation to use of medicines.

If the drug marketed is found to contain significant toxic effect or serious adverse drug reactions (SADRs) the drug is withdrawn from market or restricted to certain uses. If it is safe, then marketed overall.

The international collaboration in the field of pharmacovigilance involves WHO international drug monitoring program which record and report adverse effect of drugs in patient.

The proper database management of pharmacovigilance study to meet public expectations and the demands of modern public health1..

Keywords: *Pharmacovigilance, ADR, Adverse drug reactions, Medicine Safety etc*

1. INTRODUCTION

Pharmacovigilance is simply the science which study and monitor of the newly launched drug effect on patients in relation to identification, evaluation, understanding and prevention of adverse drug reactions (ADRs) of that particular drug or in combination of other drug[3].

ADRs is simply an unwanted effect of drug.

Adverse drug reaction can be defined as an unintended noxious reaction that occurs at doses normally used in humans for prevention, prophylaxis, diagnosis or treatment or to modify physiological functions.

No doubt medications have proven to be a blessing to mankind, fighting illness as well as suffering without a doubt. Medicines, like most other useful products, have potential dangers correlated with their use, which are known as Adverse Drug Reactions (ADRs)[5].

Once the drug/medicine sale license is granted after all phase of clinical trail and controlled research which also consists of pharmacoepidemiologic studies to evaluate the effectiveness, safety, and utilization of the drug in large populations, under real-life conditions[4].

All over the world clinical trial procedures are generally tightly regulated. But in practical all procedures do not accurately represent how the product will be used in real-world situations and their outcome is sometime unpredicted.

Drug post-marketing surveillance programs are essential for monitoring the occurrence of ADRs in both short period and long period, as the data derived from pharmacovigilance may encourage drug regulatory decision making. The results confirm or disprove the effectiveness of the drug in clinical practice (confirmation of the therapeutic effect), determine whether approved uses should be expanded or restricted, provide data on the incidence and clinical relevance of adverse events and untoward drug-drug interactions (pharmacovigilance), and clarify the medico economic consequences of

introducing the drug (Pharmacoeconomics)[4].

In the mid-nineteenth century, pharmacovigilance originated as a discipline devoted to the identification, evaluation, awareness and avoidance of adverse drug reactions as well as other medication related problems.

Collecting different data relevant to a product's conduct that is, drug life cycles, both pre-market and post-market, is the most important feature of a concern for public safety[9].

A major tragedy could have been avoided if the drug had been properly checked in preclinical safety trials.

Onset of ADRs.

Early Reaction

At the beginning of the treatment patient may experience some reaction which become tolerated with time[8].

Late Reaction

This occurs rarely or not at all at the beginning of treatment. Usually, late reaction appears after repeated administration of the drug[8].

2. WHY PHARMACOVIGILANCE IMPORTANT

Clinical trials of Phases I through III are conducted in a limited number of individuals usually under favourable conditions, but when drug/medicines launched to market it is very unpredictable how the drug/medicine will work under different conical conditions and in different places[9].

FACTOR AFFECTING ADR

The majority of ADRs occur because of the extension of the desired pharmacologic effects of a drug, often due to the substantial variability in the pharmacokinetics and pharmacodynamics seen among patients.

The factors which affect ADR can be classified in three categories.

Patient related factors.

Drug related factors.

Other Factors.

1. Patient related factors.

All drugs can produce ADRs, but not all patients develop the same level and type of ADRs. Various sub factors affect the patient for ADS.

Age:

Paediatric patients are particularly vulnerable to ADRs because drugs are less likely to be studied extensively in these cases.

Drug absorption and metabolism are more variable and less predictable in paediatrics & elderly patients

Elderly patients are likely to have many health problems and thus take several prescriptions and over the counter drugs.

Gender:

The biological differences of males and females affect the action of many drugs.

The anatomical and physiological differences are body weight, body composition, gastrointestinal tract factors, liver metabolism, and renal function.

Women in comparison to men have lower bodyweight and organ size, more body fat, different gastric motility and lower glomerular filtration rate. These differences can affect the way the body deals with drugs.

One of the most consistent observations in health research is that women report symptoms of physical illness at higher rates than men.

Maternity Status:

Pregnancy has an impact on drug treatment. Not only are women affected by the drug, but the fetus will also be exposed to medicine in womb.

acidity and tone of GIT are decreased during pregnancy and this might interfere with drug absorption.

Allergy and Disease Related Factors :

Every individual have different allergy profile.

Drug sensitivity may differ from patient to patient.

Drug independent cross-reactive antigens can induce sensitizations, which can manifest as a drug allergy.

Presence of multiple disease conditions at same time predisposes patient to drug-disease interaction which may eventually lead to ADRs.

Weight :

After a drug is absorbed into the bloodstream, it rapidly circulates through the body. As the blood recirculates, the drug moves from the bloodstream into the body's tissues. Once absorbed, most drugs do not spread evenly throughout the body.

Drug half life highly depend in body weight, drug dose has to be adjusted according to the weight.

Lower weight lower drug and higher weight higher drug required.

For example T. Paracetamol 500 mg may may show different action on patient with 40 kg weight and patient with 100 kg weight.

Obese people may store large amounts of fat-soluble drug, whereas very thin people may store relatively little.

Personal Habits: Drinking & Smoking

Taking alcohol with certain drugs can cause many ADRs like nausea, vomiting, headaches, drowsiness, fainting, loss of coordination and hypotension.

Alcohol affects the metabolism of many drugs and it facilitates the development of ADRs. Alcohol drug interaction refers to the possibility that alcohol may change the intensity of the development of ADRs.

Alcohol might affect the functionality of the liver causing liver cirrhosis and liver hepatitis which in turn affect the ability of this organ to metabolize drugs especially drugs metabolized by the liver and drugs which have first pass metabolism.

Smoking affects the metabolic process by affecting liver enzymes.

Smoking is one of the risk factors of many diseases like peptic ulcer, cancer and cardiovascular diseases.

Cigarette smoking also reduces the effect of beta blockers.

Cigarette smoking may decrease the rate of insulin absorption after subcutaneous administration.

Drug related factors.

Drug Dose and Frequency

Dose of medication, frequency of administration and time of the day at which the drug is administered significantly affect the occurrence of ADRs.

Administering under dose or overdose of medication, increasing or decreasing frequency of administration, changing the appropriate time of the day to administer the medication can cause patient harmful drug effects[7].

Actions of drugs whether beneficial or harmful depend mainly on the dose administered.

Frequency of drug administration, changing the appropriate time of the day to administer the medication can cause patient different drug effects for example - Aspirin when taken at night yield better anti-platelets action, diuretics like bendrofluazide should not be taken at night to prevent sleep disturbances[12].

Poly Pharmacy

Taking several drugs, whether prescription or over-the-counter, contributes to the risk of having an ADR.

Polypharmacy is a result of many conditions; patients might suffer from more than one disease especially among the elderly. Patients might seek more than one prescriber at the same time for different diseases or acute or chronic conditions[9].

It involves prescription of too many medications at same time for a single patient than clinically required.

Self Medication

Taking self medication or over the counter medication with previous prescription medicines may also result in ADRs.

Self medication create lack of coordination between physician and pharmacists and can turn in to ADRs.

Other Factors.

Race and Ethnicity

Ethnic background is believed to be controlled by genetic factors.

Ethnic background is controlled by genetic factors, which makes the inter-individual differences due to polymorphisms in

genes[8].

Ethnicity is an important demographic variable contributing to interindividual variability in medication metabolism and response[8].

Food-Drug Interactions –

This happen when something you eat or drink changes how a medicine works, either by boosting, blocking, or altering its effects, often by affecting absorption, metabolism, or the drug's action in the body.

As food habit changes region to region the effect of same drug with different foods may lead to ADRs.

Environmental Factors

Factors like environmental temperature can influence the occurrence of certain reactions.

Certain drugs may change there potency depending on temperature and moisture which can lead to the ADRs.

3. HOW PHARMACOVIGILANCE CAN MINIMIZE THE RISK OF ADR

Preventing ADRs is a critical part of clinical practice. healthcare providers must have an awareness of and access to information related to ADRs. To minimize such events, they must develop a rational approach[12].

Strategies to minimize the risk include[9]:

Medication review: Regularly reviewing a patient's medication list to identify potential interactions or unnecessary drugs[9].

Patient education: Providing patients with information about their medications, including potential side effects and what to do if they experience them[9].

Monitoring: Regular monitoring of patients on high-risk medications or those with known potential for ADRs, such as regular liver function tests for patients on certain drugs[9].

Dose adjustment: Individualizing drug dosages based on patient factors, such as age, weight, and kidney function[9].

Avoiding polypharmacy: Reducing the number of medications whenever possible, especially in older adults[2].

THE ROLE OF HEALTHCARE PROFESSIONALS

Healthcare professionals has a vital role in preventing and managing ADRs.

Standardize prescription writing: Physicians must standardize prescriptions writing as per standards to avoid ARDs. Standardization like age, height weight may be helpful for pharmacist to crosscheck the dosage. Standardization of prescription will also help to reduce the drug-food and drug-drug interactions[2].

Computer and Software: Healthcare professionals like doctors, pharmacists and pathologists must use computer and software-based programs to write prescription and make billing or to repot about test. Computer and software-based programs may help to reduce ADRs to a large extent[13].

Educate patients more about his treatment : Healthcare professionals must educate patients about the possible effect of drug. Healthcare professionals must tell patient about DO and DONTS while taking medication[5].

THE ROLE OF PATIENTS

Patients also play a vital role in preventing and managing ADRs. They should

Be informed: Understand the medications they are taking, including potential side effects.

Communicate: Inform healthcare providers about any past ADRs, allergies, or unusual symptoms they experience while on medication.

Adhere to medication plans: Follow prescribed medication regimens carefully, including dosages and schedules.

4. CONCLUSION

Pharmacovigilance is very important role in addressing the risks of post-marketing sale of new launch drug/medicines.

Adverse Drug Reaction (ADR) of drugs happen commonly, and their reporting is important for the early recognition and prevention of ADRs.

Pharmacovigilance not only will help in generating signals but also helps the regulatory authorities/healthcare professionals in making the policy decision[6].

When adverse effects and toxicity occur, particularly when they are previously unknown, they must be registered, evaluated and their importance effectively communicated to those with the ability to interpret the data.

Proper pharmacovigilance study ensure that pharmaceutical products of good quality, protection and effectiveness are used rationally which will minimise the risk of harm to patients, which will also furthermore help in treatment decisions. Study also increases patient confidence, ensure that risks associated with drug which are expected.

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