WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Review on Pharmacovigilance Study of Theophylline as a Antiasthamatic Agent in A Patient of Asthama

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ABSTRACT :

The present study was conducted to evaluate adverse drug reactions associated with antiasthmatic agent theophylline. Bronchial asthma is one of the most common chronic diseases in the world affecting around 334 million people. Management of bronchial asthma includes multidrug therapy for long duration, which leads its association with adverse drug reactions (ADRs). Adverse drug reactions (ADRs) are a global health problem and a leading cause of death, illness and injury in economically developed countries like India. ADRs associated with theophylline can result in non-compliance and therapeutic failure. The present study was aimed to identify the ADRs caused by theophylline drug. ADR reporting also help to minimize morbidity and improve patient compliance and achieved the better therapeutic outcome.

Objective :

To detect, access, understand and prevent adverse effect and any other possible drug related problems

The aims of pharmacovigilance are to:

- Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions;
- Improve public health and safety in relation to the use of medicines;
- Detect problems related to the use of medicines and communicate the findings in a timely manner;
- Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, leading to the prevention of harm and maximization of benefit;
- Encourage the safe, rational and more effective (including cost-effective) use of medicines;
- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

PHARMACOVIGILANCE

INTRODUCTION:-

Pharmacovigilance was officially introduced in December 1961 with publication of a later (case reports) in the lancet by w.mc bride, the Australian doctor who first suspected a casual link between serious fatal deformities and thalidomide a drug used during the pregnancy. Thalidomide used as anti-emetics and sedative agent in pregnant women.

In 1968, the world health organization (WHO) promesed the programme for International drug monitoring a pilot project to centralized world data on nóverse drug reaction, the main aim of the WHO programs" was identify the earliest possible PV signal pharmacovigilance is the science and activities related to the detection, ment understanding and prevention of adverse effect or any other possible dnig problems.

Pharmacovigilance is defined as the pharmacological science relating to the detect assessment, understanding and prevention of adverse effects, particularly long-term and short term adverse effects of medicines".

Pharmacovigilance also known as drug safety und abbreviated PV or Phy. The word "Pharmacovigilance are: Pharmacon (Greek word for "Drug") and vigilance (Latin word for "to keep watch"). The aims to improve patients care and safety with respect to the use of medicines and other medicines interventions and also contributes to the risk benefit analysis of the medicines.

Terminology:- Adverse drug reaction:-

An adverse drug reaction (ADR) is any noxious, unintended and undesired effect of a drug which occurs at a dose used in human for prophylaxis, diagnosis, therapy or modification of physiological function.

Marketing surveillance:-

Post-marketing surveillance (PMS) is the practice monitoring the safety of a pharmaceuticaldrug or device after it has been released in the market.

OBJECTIVES

1. To create a nation – wide system designed for patient safety reporting.
2. To identifie and analyse latest signal (ADR) in the Reported cases
3. To research the benefit risk ratio of marketed Medicaments.
4. To generate evidence based information on safety of Medicines
5. To support the regulatory agencies in the decision Making process on use of medicines.
6. To communicate the safety information on use of Medicines to various stakeholders to mini,ise the Risk.
7. To emerge as a national centre of excellence for Pharmacovigilance activities
8. To collaborate with other national centres for the Exchange of information & data management.
9. To provide training & consultancy support to other national Pharmacovigilance centres located across Globe.
10. To create awareness amongst healthcare Professional about the importance of ADR reporting in India.
11. Support the CDSCO for formulating safety related regulatory decisions for medicines.
12. To promote rational use of medicine.
13. Study of purpose of pharmacovigilance and drug alert
14. Study of pharmacovigilance and drug alert correlation.

CLINICAL RESEARCH

Clinical trials:- A systematic study on pharmaceutical products in identities a human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the objective of ascertaining their efficacy and safety.

Components

- ❖ Case-control study (Retrospective study).
- ❖ Prospective study (Cohort study).
- ❖ Population statistics.
- ❖ Intensive event report.
- ❖ The spontaneous report in the case is the population of the single case report.

Constitution and Objectives of Pharmacovigilance Program Of India (PVPI)

Objectives

- To create a national-wide system for patient safety reporting
- To identify and analyze new signal from the report cases
- To generate evidence based information on safety of medicines. **(4)**

List of National Adverse Drug Monitoring Centres(AMCs)

- Department of Pharmacology, PGIMER, Chandigarh

- Department of Pharmacology, R.G. Kar Medical College, Kolkatta
- Department of Pharmacology, Lady Hardinge Medical College, New Delhi
- Department of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Parel, Mumbai
- Department of Clinical & Experimental Pharmacology, School of Tropical Medicine,
- Chittaranjan Avenue, Kolkata
- Department of Pharmacology, JIPMER, Pondicherry.
- Department of Clinical Pharmacy, JSS Medical College Hospital, Karnataka
- Department of Pharmacology, Medical College, Guwahati. Assam
- Institute of Pharmacology. Madras Medical College, Chennai
- Department of Pharmacology, SAIMS Medical College, Indore-Ujjain. **(5)**

Drugs Controller General of India (DCGI)

Defination:- Drugs Controller General of India (DCGI) is the head of department of the Central Drugs Standard Control Organization of the Government of India responsible for approval of licences of specified categories of drugs such as blood and blood products, IV fluids, vaccines, and sera in India.

Functions:-

1. Pharmacovigilance (PV) plays a key role in the healthcare system through assessment, monitoring and discovery of interactions amongst drugs and their effects in human.
2. DCGI lays down the standard and quality of manufacturing, selling, import and distribution of drugs in India.
3. Preparation and maintenance of national reference standard. To bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
4. Training of Drug Analysts deputed by State Drug Control Laboratories and other Institutions.

Central Drug Standard Control Oraganization

Defination:- CDSCO is the regulatory agency of India, under which the national pharmacovigilance program runs.

Functions:-

1. Approval of new drugs and clinical trials
2. Import Registration and Licensing
3. License approving of Blood Banks, LVPS, Vaccines, r-DNA products & some Medical Devices (CLAA Scheme)
4. Amendment to D &C Act and Rules
5. Banning of drugs and cosmetics
6. Grant of Test License, Personal License, NOCs for Export
7. Testing of New Drugs **(1)**

CONCLUSION:

ADRs reporting which will help in promoting safer drug use, information to the healthcare professionals. Improve the quality of patient care and educate to increase awareness. The adverse drug reaction monitoring and reporting programmes or pharmacovigilance programme aim is to identify the risks associated with the use of the drugs. This information may be useful to identify and to minimize the preventable ADRs. Many time patients discontinue their treatment because of the suffering of the adverse drug reaction. Some time it may be very dangerous for the patient as well as society. So now the time has come to aware the general public too for the reporting the adverse drug reaction to nearest hospital or ADR monitoring centre or to the healthcare professionals. The goal of this study is to assess the expectedness, seriousness and severity of adverse drug reactions during chronic obstructive pulmonary disease therapy by using drug theophylline.

In conclusion, the medicines for Asthama disease cause many serious adverse drug reactions, most of them were unexpected, lacking in the short product characteristics. Appropriate reporting of adverse drug reactions is necessary to decrease the risk of patients and healthcare system.