BioGecko

Vol 12 Issue 03 2023
ISSN NO: 2230-5807

Pharmacovigilance – An Overview

Dr M.Subhathra[1]Dr A.Sureka[2]
1.Program Assistant, Peripheral pharmacovigilance centre, GSMC, Chennai-105.
2. Resident Medical officer, National Institute of siddha, TamabaramSanotorium, Chennai.

Abstract
Pharmacovigilance (PV) is recent discipline in the pharmaceutical Industry. PV touches the disciplines in the development enterprise. This growth has come an increased awareness and interest in the medical community about the roles that PV plays. This article provides insights into the background and inner workings of PV.This narrative review covers the core PV activitiesin India from its origin toand proposalsto development of PV.Signal assessment is mainly performed to analyse the cause and effect by using WHO scale and Narranjo scale of probability.It's a very vital and complex process.This review indicates the current scenario and also discussesthe various strategies and proposals to build and maintain the implement a robust PV system and to improve the process of ADR reporting in the country.

Keywords: Pharmacovigilance, Adverse drug reaction, Adverse events.

Introduction

PV started about 170 years ago,although it was not yet named at such that time.It is the structured activity in the professional Health field,with important social and commercial implications aimed at monitoring the risk ratio of drugs,improving patient safety and quality of life. PV is defined by the European commission as the process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines.

History of pharmacovigilance

Pharmakon(Greek)medicinal substance and *vigilia (*Latin)-to keep watch.The history of pharmacovigilance started on Jan 29,1848when a young girl Hannah Greener from theNorth of England died after receiving chloroform anaesthetic before removal of infected toe nail.Sir James Simpson discovered had discovered that chloroform was a safer and powerful anaesthetic,and he had introduced it in clinical practice, but it was impossible to identify what killed her.Probably she died of a lethal arrythmia or pulmonary aspiration.The results were published in The Lancet in1893.(1)

The US Federal Food and Drug Act was formed on June 30 1906, and it established that drugs must be pure and free of contamination. In1911, this organizations forbade false therapeutic indications of drugs.In 1937, there were 107deaths in the USA, because of the use of sulphanilamide elixir,containing diethyl glycol as a solvent. This solvent was considered the cause of deaths, but the manufactory companies does not aware about the toxicity at that time.

In 1961, a big change of European pharmacovigilance happened following the tragedy of thalidomide. DrMc.Bride,an Australian doctor ,wrote a letter to the editor of Lancet Journal, in which he suggested a connection between congenital malformation of babies and thalidomide.In fact, he observed that the incidence of congenital malformations of babies had increased up to20% in women who had taken thalidomide during pregnancy. At the same time,during a paediatric convention in Germany Dr.Lenzsuggested a corelation between malformations and thalidomide and his suspect was published in a German Journal .In 1973, A retrospective study showed that corelation between that congenital malformations of babies and the ingestion of thalidomide during pregnancy. In USA,the tragedy of thalidomide was not observed,because Dr Kelsey showed strong doubts about the safety of

thalidomide during pregnancy.The tragedy of thalidomide brought to light many problems and critical issues,in particular the reliability of animal test,the behaviour of the Industrial company and the importance of monitoring the drugs after their marketing. This tragedy changes the system of pharmacovigilance. In 1992,European society of pharmacovigilance was turned into the international society of pharmacovigilanceand enhance all aspects of the safe and proper use of medicine.(2)

Pharmacovigilance AS&U Drugs present scenario and Future Aspects

NATIONAL PHARMACOVIGILANCE CENTRE

The central drugs standard control organisation (CDSCO) has initiated a country wide pharmacovigilance under the aegis of DGHS, Ministry of Health and Family Welfare Government of India.(3)

The program is coordinated by the National Pharmacovigilance centre at CDSCO.The National centre is operating under the supervision of the National Pharmacovigilance Advisory committee to recommend procedures and guidelines for regulatory intervention. (3)

NATIONAL PHARMACOVIGILANCE PROGRAMS

The National pharmacovigilance programme was inaugurated on November2004 at New Delhi, sponsored by the World Health Organisation and funded by the World Bank,because fully functional in January 2005.The programme aims to faster the culture of ADR Notification in its first year of operation and subsequentlyaims to generate broad based ADR data on the Indian population and share the information with global health care community through WHO-UMC. The Nationwide programme, sponsored and coordinated by the country'scentral drug regulatory agency-central drug standard control organizations (CDSCO) to establish and manage a database of Adverse Drug Reactions(ADR'S) for making informed regulatory decisions re gradingmarketing authorization of drug in India for ensuring safety drugs. (3)

PHARMACOVIGILANCE PROGRAM IN INDIA

A National PV centre is located in the department of pharmacology.All India Institute of Medical sciences New Delhi and two WHO special centres are located in Mumbai (KEM Hospital and Aligarh (JLN Hospital).Thesecentres were to report ADRs to the drug regulatory authority ofIndia.The Major role of the centre is to monitor the ADRs to medicine marketed in India. (4)

ADVERSE DRUG REACTION

When the adverse drugs arecurious,potentially serious or clinically important, all health careworkers, including doctors,pharmacists, nurses and other health experts are requested to clarify it. It is necessary to report an adverse drug Reaction to the pharmacovigilance program even if you do not have all the facts or unsure the medicine is responsible for causing the Adverse Drug Reaction.(5)

ADR can be considered a form of toxicity;however, toxicity is most commonly applied to effects of overingestion (accidental or intentional) or to elevated blood levels or enhanced drug effects that occur during appropriate use. Side effectsare an imprecise term often used to refer to the unintended effects of a medication that occur within the therapeutic range. (6)

ADR Reporting

An Adverse drug reaction is a term used to describe the unwanted, Negative consequences sometimes associated with the use of medications.ADR is a particular typeof Adverse Effect.

Adverse Drug Reaction or an Adverse Reaction means a response to a medicine in the Humans or Animals,which is noxious and unintended,including lack of efficacy, and which occurs at any dosage and can also result from an overdose,misuse or abuse of a medicine.(6)

According to the World Health organization pharmacovigilance databases occurs mainly in patients older than 75 years of age.

Classification of ADR

Dose related ADR

This type of Adverse drug reaction is usually predictablebut sometimes unavoidable.It may occur if a dose is too high if the person is unusually sensitive to the drug,if another drug slows the metabolism of the first drug and thus increases its level in the blood.Dose related reactions may or may not be serious,but they are relatively common.(6)

Allergic Drug Reaction

Allergic drug reactionsare not dose related but require prior exposure to a drug.Allergic reactions develop when the body's immune system develops an inappropriate reaction to a drug. After a patient is sensitized later exposures to a drug produce one of several different types of allergicreactions. Sometimes drug should take skin test to help predicts allergic reactions.(6)

Idiosyncratic Adverse Drug Reaction

Usually,mechanisms are not clearly understood. This type of reaction is usually unpredictable. This reaction tends to be more seriousbut typically occur in avery small number of people.(6)

Severity of Adverse Drug Reaction

- Mild ADR
- Moderate ADRA
- Severe ADR
- Lethal

Diagnosis of Adverse Drug Reaction

- Consideration of Rechallenge
- Reporting of suspected ADRs

Treatment for Adverse Drug Reaction:

- Modification of usage
- Discontinuation of Drug or medication if necessary
- Switching to a different medication

For dose related adverse drug reactions to medications,modifying the dose or eliminatingor reducing precipitating factors may suffice.Increasing the rate of drug elimination is rarely necessary.For allergic and idiosyncratic ADR's, the drug usually should be discontinued and not tried again.(7)

Specific aim of pharmacovigilance:

1. Improve patient care and safety in relation to the use of medicines and all medicines and all medical and paramedical interventions.
2. Improve public health and safety in relation to the use of medicines,
3. Contribute in the assessment of benefit harm, effectiveness, and risk of medicine encouraging their safe rational and more effective
4. Promote understanding, educationand clinical training in PV and its effective communication to the public (6)
5. Yellow card scheme is a spontaneous reporting system. This system is one of the major International PV resources and Naranjo's probability scale is the most commonly used causality assessment method, it is structured, transparentconsistent and easy to apply assessment method.(6)

Pharmacovigilance towards Real Data and Digital Monitoring:

- To optimize and digitalize the scope of the study of critical processes of pharmacovigilance
- Continuous safety profile monitoring and benefit risk evolution of authorized medicinal products, establishing assessing and implementing risk management systems evaluating the effectiveness of risk minimisation.(8)

- Collection, possessing, management quality control follows up for missing information, coding, classification, duplicate detection, evaluation and timely electronic transmission of Individual case safety reports (ICSRs) from any source.
- Detection,investigation, and evaluation of signals.
- Scheduling, preparation (including data evaluation and quality control) submission and periodic safety update reports assessment.
- Meeting, commitments, and responding to requests from competent authorities, including provision of correct and complete information.
- Interaction between pharmacovigilance and quality effect systems.
- Communication about safety concerns between marketing authorization holders and competent authorities,in particular notifying changes to the risk benefit balance of medicinal products.
- Keep product information up to date with the current scientific knowledge, Including the conclusions of the assessment and recommendation from the applicable competent authority.
- Implementation of variations to marketing authorisations for safety reasons according to the urgency required.(8)

Collection

- Filter information
- Research in a semi-automatic mode according to the set criteria
- Receive message pending processing by a specialists
- Accumulate undifferentiated information

Structuring and preliminary analysis:

- Processing
- Management
- Quality control

Identification of the necessary missing information

- Coding
- Classification
- Detection of duplicates
- Signal management

Information Exchange

- Timely reporting of adverse reactions
- Sending reports
- Communication ecosystem solution (9)

Conclusion

Pharmacovigilance is the Integral part of the Drug regulation system. PV plays an indispensable role in the identification,assessment through various methods.ADR'S account for serious harm to the patients and even lead to morbidity and mortality. The PV databases help in the promotion of safe drug use and protection of public health safety.It's useful for systematically identifying and correlating drugs and side effects and taking corrective actions and the success of pharmacovigilance is marked by increase in use of databases to make process more active and organized.

References

1. Giuliafornasier,sarafranscescon, Roberto leone,paoloBaldo,A historical overview pharmacovigilance, International journal of clinical pharmacy40,744-747(2018)
2. Syed ZiuaurRahman,Galib Ruknuddin, History of pharmacovigilance ,Research Gate September 2022 DOI:10.21276/jpds.2021.19.01.02

3. Sandeep B Bavdekar,sunilkaranda,protocol for National pharmacovigilance program ,pub med ,feb 2006
4. Dr Sanvidhan, suke,Prabhatkosta Role of pharmacovigilance in India :An over view June 2015 Online Journal of Public Health Informatics 7(2):1-34DOI:10.5210/ojphi.v7i2.5595
5. Ragavendra,rohitsharma, d.srawan, vijayrchidrawar CMR college of pharmacy Hyderabad,A Prospective review on pharmacovigilance .
6. Daphne E.SmithMarsh pharm D,BC-ADM,CDCES,University of Illinois of Chicago,March 2023, Adverse Drug Reactions
7. Hanna Pavliuk-Gavrylova1*,Oleksandr Torhun2,Viacheslav Turok3 1 Lead of Global Regulatory Affairs at Pharmaceutical Firm "Darnitsa" 2 Regulatory Affairs Officer at Pharmaceutical Firm "Darnitsa" 3 Head of Pharmacovigilance and Medical Instructions Group at Pharmaceutical Firm "Darnitsa,New view of pharmacovigilance :towards real Data and Digital monitoring .,pub:oct 2021
8. Beninger P. (2008). Pharmacovigilance: an overview. Clin. Ther. 40, 1991–2004. 10.1016/j.clinthera.2018.07.012 - DOI - PubMed
9. Satyajeet Singh*, Jai Prakash, Dr. Naveen Goyal, Rajeev Tomar, Abhishek Chaudhary, Roorkee College of Pharmacy, Kishanpur, Roorkee, Uttrakhand, India,Review on pharmacovigilance,.published may 2015.
10. SaurabhNimesh(1),VrishAswlayan(2) Pharmacovigilance overview May 2018DOI:10.15226/2476-2431/3/1/00124