



International Journal of Life Sciences Biotechnology and Pharma Research





Review Article

PHARMACOVIGILANCE: A STEP TOWARDS DRUG SAFETY

Shiddalingesh Salimath^{1*}, Dattatri A N¹ and Lokesh Patil¹

*Corresponding Author: **Shiddalingesh Salimath** ✉ sid.kims@gmail.com

Adverse drug reactions (ADRs) are a common phenomenon. About 3-7 % of all hospital admissions are due to ADRs and in many countries ADRs rank among the top 10 leading causes of mortality. Pharmacovigilance aims at reducing the occurrence of ADRs and ensures safe and rational use of medicines.

Keywords: Adverse drug reactions, ADR, ADR monitoring

INTRODUCTION

The advances in medical science and development of newer drugs have drastically changed the scenario of present day therapeutics. However, despite all their benefits, side effects to medicines are a common phenomenon.

India is the 4th largest producer of pharmaceuticals in the world and in recent years has become an important hub for conducting clinical trials. About 3-7% of all hospital admissions are due to adverse drug reactions (Lazarou *et al.*, 1998) (ADRs) and ADRs account for the death of 15 out of every 1000 patients admitted (Gandhi T K *et al.*, 2003). In many countries, ADRs rank among the top 10 leading causes of mortality (WHO, 2004). In order to prevent or reduce harm to patients and thus improve public health, mechanisms for evaluating and monitoring the safety of medicines in clinical

use are vital. In practice this means having in place a well-organized pharmacovigilance system.

WHO defines pharmacovigilance as the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems” (WHO, 2002). It involves the continuous process of monitoring the medicines to identify the drug related adverse reactions, assessing the risks and benefits of use of medicines and providing information to the practitioners and the general public to reduce the occurrence of adverse reactions and thus encouraging the safe, rational and more effective use of medicines.

NEED FOR PHARMACOVIGILANCE

i. The information regarding the incidence and

¹ Department of Pharmacology, Karnataka Institute of Medical Sciences, Hubli - 580 021 Karnataka, India.

prevalence of adverse reactions to medicines is obtained from pre-marketing phase of the clinical trials. Clinical trials generally enrol a selected and limited number of patients. Hence rare ADRs are not detected. Drug use in special situations (notably pregnant women, children, elderly) or drug interactions are usually not studied (WHO, 2002).

- ii. Most drugs are developed in the west, hence most of the efficacy and safety data are based on Caucasians with little or no information in Indian population.
- iii. No data on ADRs due to interaction between modern medicines & herbal medicines (WHO, 2004), used commonly in our country.
- iv. ADR-related cost to the country exceeds the cost of the medications themselves.

WHY PHARMACOVIGILANCE IS ESSENTIAL

Thalidomide was introduced in 1957 and widely prescribed as harmless treatment for morning sickness and nausea. It was soon linked to a congenital abnormality (phocomelia) which caused severe birth defects in children of women who had been prescribed this medicine during pregnancy. By 1965, thalidomide had been removed from the market in most countries (Pannikar V, 2003).

WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING

WHO Programme for International Drug Monitoring was started in 1968 as a means of receiving and pooling ADR data from various countries by creating a worldwide network of

pharmacovigilance. Currently, 118 countries participate in the programme, which is coordinated by WHO together with its collaborating centre in Uppsala, Sweden (Uppsala monitoring centre). The collaborating centre is responsible for maintaining the global ADR database, VIGIBASE. The WHO Collaborating Centre analyses the ADR reports in the database to identify early warning signals of new adverse reactions to medicines, evaluates the hazards and provides guidelines for safer and more effective medicines.

FRAMEWORK FOR PHARMACOVIGILANCE IN INDIA

The Central Drugs Standard Control Organization (CDSCO), New Delhi, under the aegis of Ministry of Health & Family Welfare, Government of India has initiated a nation-wide pharmacovigilance programme with national coordination centre (NCC) in Ghaziabad, Uttar Pradesh for monitoring Adverse Drug Reactions (ADR) in the country (Rahman S Z and Khan R A, 2011). Presently All Medical Council of India (MCI) recognized medical colleges are enrolled as ADR Monitoring Centres (AMC). ADR Monitoring Centre (AMC) conveys the reported cases of ADRs to national coordination centre (NCC) by uploading the ADR reports in VIGIFLOW (a web-based data management system for reporting ADRs).

WHAT HAPPENS TO THE INFORMATION SUBMITTED?

National coordination centre analyses the data and forwards it to the Global Pharmacovigilance Database (VIGIBASE) managed by the WHO Uppsala Monitoring Centre in Sweden. The

reports are periodically reviewed by the National Coordinating Centre. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines. The information is submitted to the steering committee constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

National pharmacovigilance centres are responsible for

- Identifying and analysing new signal from the reported ADR cases.
- Analysing the benefit - risk ratio of marketed drugs.
- Generating evidence based information on safety of medicines.
- Supporting drug regulatory agencies to take decisions based on reported ADRs.
- Alerting prescribers, manufacturers and the public to new risks of adverse reactions.
- Promoting rational use of medicines.

OUTCOME OF PHARMACOVIGILANCE - THE CASE OF CERIVASTATIN

Cerivastatin was a lipid lowering agent approved in 1997. By 2000, a total of 549 cases of rhabdomyolysis were reported with cerivastatin use to WHO Uppsala Monitoring Centre, Sweden. Consequently an advisory for caution was issued for cerivastatin use. On 8th August 2001, the manufacturer voluntarily withdrew the drug from the market citing increased risk of rhabdomyolysis (Demortain D, 2011).

PHARMACOVIGILANCE IN OUR INSTITUTE

Karnataka Institute of Medical Sciences (KIMS), Hubli is a recognised regional pharmacovigilance centre under the National Pharmacovigilance Programme of India. The pharmacovigilance unit, under the aegis of Department of Pharmacology, is functioning at ART centre of the institute. The standard ADR forms for collecting the ADR reports have been provided to all the wards along with the copy of instructions to fill the form. The hospital staffs are required to report the occurrence of ADRs by filling the ADR forms and forwarding them to pharmacovigilance unit. The pharmacovigilance staff will then do the causality assessment of the reported ADRs and convey the information to the National Coordination Centre by uploading into VIGIFLOW system.

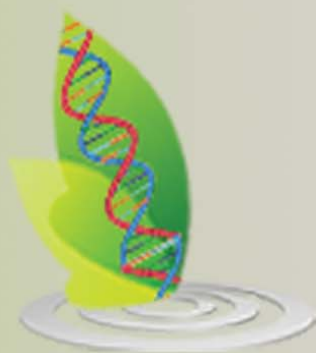
Since the establishment of pharmacovigilance centre in our institute a total of 20 cases of ADRs have been reported. 10 cases of ADRs were reported from the department of general medicine, 5 from dermatology, 4 each from obstetrics-gynaecology and cardiology, and 2 from ophthalmology. Nevertheless the reporting of ADRs has not been satisfactory in our institute.

CONCLUSION

Underreporting of ADRs is still a major limitation for the proper implementation of pharmacovigilance system in our country. The reasons may vary from the heavy workload, apathy, lack of awareness or unwarranted fear of legal liability. The aim of this article is to create awareness about pharmacovigilance among doctors, medical students and other healthcare professionals so as to improve the overall safety of medications and consequently the quality of healthcare delivery.

REFERENCES

1. Demortain D (2011), "Scientists and the Regulation of Risk", Massachusetts: Edward Elgar Publishing.
2. Gandhi T K, Weingart S N and Borus J (2003), "Adverse drug event in ambulatory care", *N Engl J Med*, Vol. 348, pp. 1556-64.
3. Lazarou J, Pomeranz B H and Corey P N (1998), "Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies", *JAMA*, Vol. 279, pp. 1200-5.
4. Pannikar V (2003), "The return of thalidomide: new uses and renewed concerns", *WHO Pharmaceuticals Newsletter*, Vol. 2, p. 11.
5. Rahman S Z and Khan R A (2006), "Environmental Pharmacology: A new discipline", *Indian J Pharmacol.*, Vol. 38, No. 4, pp. 229-230.
6. WHO (2004), *Pharmacovigilance: Ensuring the safe use of medicine* WHO Collaborating Centre for International Drug Monitoring, Geneva, Switzerland.
7. WHO (2002), *Safety of medicines: A guide to detecting and reporting adverse drug reactions*, World Health Organization, Geneva.
8. WHO (2002), *The importance of pharmacovigilance: Safety monitoring of medicinal products*. WHO Collaborating Centre for International Drug Monitoring, Geneva, Switzerland.
9. WHO (2004), *WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems*, World Health Organization, Geneva.



International Journal of Life Sciences Biotechnology and Pharma Research

Hyderabad, INDIA. Ph: +91-09441351700, 09059645577

E-mail: editorijlbpr@gmail.com or editor@ijlbpr.com

Website: www.ijlbpr.com

