ejpmr, 2022,9(6), 399-400

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

PHARMACOVIGILANCE: A REVIEW

Dr. Ram Garg[1]*, Dr. Vandana Sharma[2], Ashok Kumar Sharma[1], Gandeep Jasrotia[3], Shumayla Naaz[3], Gyanendra Sharma[3], Rakesh Gurjar[3] and Vijendra Pal Singh[3]

[1]Professor, Arya College of Pharmacy, Kukas, Jaipur.
[2]Principal, Arya College of Pharmacy, Kukas, Jaipur.
[3]Research Scholar, Arya College of Pharmacy, Kukas, Jaipur.

***Corresponding Author: Dr. Ram Garg**

Professor, Arya College of Pharmacy, Kukas, Jaipur.

Article Received on 21/04/2022 **Article Revised on 11/05/2022** **Article Accepted on 01/06/2022**

ABTRACT

Pharmacovigilance (PV) is an important area for the safety and ensuring that the patients safety in every aspect of the drugs being taken or injected. As India is still in its growing stage; lot of research and study to be done and to learn, in the field of PV, in ensuring to insure the safety. As we know Under-reporting is the main problem in India in terms of adverse drug reaction (ADR). There is an increasing number of patients owing to adverse effects of drugs and it becomes a challenge to find out the exact cause the ADRs when a patient in treated with multiple drugs simultaneously. In this review, we will explore the different types to assess ADR and to how its causative agents.

KEYWORD: Pharmacovigilance (PV), adverse drug reaction (ADR).

INTRODUCTION

Pharmacovigilance (PV), also called as drug safety, it is science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term, and short term side effects of medicines. PV is an important and integral part of clinical research The under-reporting of adverse drug reactions (ADRs) is the major set-back worldwide which may be attributed to the lack of time and report forms. It has been known that the world health organization (WHO) has initiated the program of reporting all adverse reactions possessed by the drugs. Moreover, its concerns have been widened to include the herbal drug products, traditional and complementary medicines, blood products, biologicals, medical devices, and vaccines. In addition, PV possesses various roles such as identification, quantification, and documentation of drug-related problems which are responsible for drug-related injuries. Further, national PV programmes have been introduced which occupies a prime role in increasing the public awareness about drug safety. This review article explains the need and importance of PV in daily lives of doctors and patients and the pharmaceutical industry.

Importance of Pharmacovigilance

PV deals with the complex process explaining the nature of ADR occurred in a patient taking drug it can be either oral or parenteral or intravenous (I.V) drugs. During the production of drugs they underwent a whole array of tests worldwide and also conduct clinical trials in animals and human subjects to assess the safety of the drug for a particular disease and to know the exact side effects associated with it.ADR decrease the lifespan of the human being by, increase hospitalization, increases the mortality.

Aims of PV

PV is used for the assessment of side effects caused by the drugs whether it is caused by oral drugs; parenteral drugs or I.V. drugs. These drugs are pretested for ADRs before it is being marketed worldwide. PV has a key role in assessment, detection and identification of drugs which caused a particular ADRs and the mechanism by which it caused the injury. But to fulfill these requirements of finding and eliminating, a side effect is the responsibility of the doctors involved in the case; nurses, health workers, residents and proper guidance of the patients themselves help it to alleviate the root cause of ADR

Methods used in PV

Many researchers developed different methods of causality assessment of ADRs by utilizing different criteria like chronological relationship between the administration of the drug and the occurrence of the ADR, screening for non-drug related causes, confirmation of the reaction byin vivo or in vitro tests, and antecedent information on homogeneous events attributed to the suspect drug or to its therapeutic class, etc., to define ADRs in different categories. Currently, there is no universally accepted method for assessing causality of ADRs. Currently, there are many algorithmic

methods of causality assessment but no single algorithm is accepted as the gold standard because of the short coming sand discordances that subsist between them. We would explicate them in short as listed below.

This rule of thumb has been used by the French government agency since 1977. The way of doing thing separates an intrinsic imputability (possible case between abused substance and dispassionate event)from an extrinsic imputability (bibliographical data) by the agency of seven criteria (three connected and four semiological) in two different tables. The criteria are (i) drug challenge, (ii) dechallenge and (iii) rechallenge by the overall score of four possible categories. The semiological criteria are (i) semiology (clinical signs) using per se (suggestive or other), (ii) favoring component, (iii) arbitrary non-drug related (none or possible), and (iv) laboratory tests show with three possible outcomes (positive, negative or no test for the event-drug pair). Scores are grouped as possible and dubious.

This method developed to assess the teratogenic potential of drug. The first sections of the algorithm sanction for the drug to be omitted if not implicated in the inception of the abnormality. The second section weighs the bibliographical data. The three questions consider alternative etiological candidates other than the drug; chronology of the suspect drug and other bibliographical data, to arrive at a conclusion on causality.

Australian method involves the evidence which helps in to draw the conclusion, such as timing, and laboratory information from case reports presented and the antecedent cognizance on the suspect drug profile is deliberately omitted in the assessment. Probabilistic or Bayesian approaches. It utilizes concrete findings in a case to transform a prior into a posterior probability of drug causation. The prior probability is calculated from epidemiological information and the posterior probability cumulates this background information with the evidence in the individual case. It is open-ended approach with no circumscription to the amount of case details that can be assessed utilizing this method. Simultaneous assessment of multiple causes can be assessed.

WHO-Uppsala monitoring centre (UMC) causality assessment criteria

The WHO-UMC causality assessment method includes the following criteria

- Certain-adverse event and the time relationship associated with it
- Probable/likely-unlikely to attribute the other drugs or diseases
- Possible-this can be explained by the drug intake or another disease
- Unlikely-adverse event can be explained with the time relationship associated with it but its not impossible
- Conditional/unclassiϭied-more data in needed to make a proper assessment
- Unassessable/unclassiϭiable-an adverse event is suggested but more data are needed to make an assessme

CONCLUSION

PV remains a dynamic part of the clinicians and the general population. After the appearance of these adverse drugs effects, it is very essential that these are reported timely and analyzed. Not only the doctorsshould be aware of the PV programme but the patients themselvesshould be made aware of this so self-reporting is increased and theburden on the clinicians is also reduced. India is still in the growingphase of PV and more reporting is necessary to reach the world'sstandard of reporting these adverse events to provide effective druguse in children's and pregnant women which is one of the mostvulnerable populations of all. The PV programme must be able toidentify these adverse events timely in the coming years with the helpof clinicians, patients, and the pharmaceutical industry to help shape the safety of patients themselves.

REFERENCES

1. Pipasha, B., Arun, K.B. Setting standards for proactive pharmacovigilance in India: The way forward", Indian J pharmacol, 2007; 39(3): 124-128.
2. Kumanan, R., Sudha, S., Vijayashre, P., Charumath, S., Gowridevi, K.C., Mahesh, M. Imperative Approach on pharmacovigilance in Indian systems of medicines", International journal of pharma sciences and Research (ijpsr), 2010; 1(9): 378-390.
3. Deepa, A. „ Pharmacovigilance obligations of the pharmaceutical companies in India", India J pharmacol, 2008; 40: S13-S16.
4. Zhengwu Lu. information technology in pharmacovigilance : Benefits, challenges, and future directions from industry perspectives", Drug, Health Care and patient safety, 2009; 1: 35-45.
5. WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO, 2004.
6. WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO, 2004.
7. WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO, 2004.
8. WHO, Safety of medicines in public health programmes: pharmacovigilance an essential tool, WHO, 2006.
9. WHO, Safety of medicines in public health programmes: pharmacovigilance an essential tool, WHO, 2006.