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Review article

Toxicovigilance: a new approach for toxicological screening, quality control and regulation of irrational herbal drugs

Neetesh K Jain*[1], Suman Jain[1], S.C.Mehta[2], S.D.Tonpay[2]

[1]SOS in Pharmaceutical Sciences, Jiwaji University, Gwalior (M.P.), India.
[2]Department of Pharmacology, G. R. Medical College, Gwalior (M.P.), India.

Abstract

Herbal medicines are now in great demand in the developing world for primary health care not because they are inexpensive but also for better cultural acceptability, better compatibility with the human body and minimal side effects. However, recent findings indicate that all herbal medicines may not be safe as severe consequences are reported for some herbal drugs. Most herbal products on the market today have not been subjected to drug approval process to demonstrate their safety and effectiveness. Thus, toxicovigilance can contribute for toxicological screening, quality control and regulation of herbal drugs including hazard identification and risk assessment by providing medically validated data which are often overlooked in the process of risk assessment. As pharmacist and researchers continue to explore the safety and effectiveness of herbal medicines, more is learned about both their promises and their pitfalls. At the same time, legislators at the national level should continue to press for effective laws to protect consumers from potentially harmful herbal drugs.

Key words: Toxicovigilance, ADR of Herbal drugs, Quality control, Pharmacovigilance

***Corresponding Author: Neetesh K Jain,** Ph.D Research Scholar, G. R. Medical College, Jiwaji University, Gwalior

1. Introduction

Toxicovigilance

Toxicovigilance is the active process of identifying and evaluating the toxic risks existing in a community, and evaluating the measures taken to reduce or eliminate them. It involves the analysis of poisons centre enquiries to identify whether there are specific circumstances or agents giving rise to poisoning, or certain populations suffering a higher incidence of poisoning. Toxicovigilance can also reveal whether there is an emerging toxicological problem resulting from, for example, the reformulation of a product or a change to its packaging or labelling, the availability of a new drug of abuse, or an environmental contamination [1].

Toxicovigilance is a relatively new approach in medical toxicology; no widely accepted definition is available. Its scope primarily encompasses the active detection, validation and follow-up of

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clinical adverse events related to toxic exposures via household, occupational or environmental chemicals and products [2].

It is clear that the herbal industry needs to follow strict guidelines and that regulations are needed. The food and drug administrations that regulate prescription drugs only review a herbal product if the item is suspected of being harmful or if the label contains a medical claim. Although research is being done, it is very limited and only a few herbal drugs have been studied adequately by well-controlled clinical trials. Even though evidence should always be presented to support claims of products, most herbs are still marketed with little or no scientific research [3, 4, 5, 6, 7, 8]. To be registered as drugs, these products need to be tested to prove their safety and clinical efficacy. However, so far, few programs have been established to study the safety and efficacy of herbal medicines as originally proposed in the WHO guidelines for the assessment of herbal medicines [9, 10, 11, 12].

Toxicity of herbal drugs

For several reasons it is not possible to establish absolute safety standards for herbal preparations based solely on epidemiological studies. First, these types of studies would be costly. Second, there is little published data in countries where the major use of medicinal plants occurs and thus general standards based on a limited number of reports would have little meaning. Third, the exact identification of the products implicated in side effects claimed for medicinal plants is usually lacking. In spite of these inadequacies, there are a number of general comments that can be made with regard to avoiding potential serious side effects from herbal medicines.

In certain countries, such as Taiwan, herbs can be obtained from temples, night markets, street vendors, herbal stores, neighborhoods, or relatives, and from traditional medicine practitioners. Ordinary people recommend the medicines to others without safety considerations. The general public and many practitioners also believe that the herbs are nontoxic. Apparently, this cultural style/concept needs more attention in terms of drug safety education. Herbs and herbal preparations can cause toxic adverse effects, serious allergic reactions, adverse drug interactions, and can interfere with laboratory tests [13].

Quality control and regulation of herbal drugs

The quality of consumer information about the product is as important as the finished herbal product. Warnings on the packet or label will help to reduce the risk of inappropriate uses and adverse reactions [14]. It is axiomatic that pregnancy should be a time of minimal medical intervention, and herbalists in particular regard pregnancy as a “contraindication” to taking herbal medicines. It is a widely held myth that modern drugs are dangerous foreign chemicals with side effects, while herbals are natural, gentle and safe. The truth is that some herbs can be dangerous and can bring about serious diseases and even lead to death. Unlike conventional drugs, herbal products are not regulated for purity and potency and this could cause adverse effects and can even lead to drug interactions [15].

Use of heavy metals is permitted in traditional medicines but in definite

concentrations, which were mentioned by ancient physicians. There are now many examples of the toxicity caused by the use of heavy metals in the preparations of traditional drugs. Lead, copper, mercury, arsenic, silver, and gold that are commonly added to these preparations, have caused toxicity on many occasions [16].

Conclusion

Toxicovigilance is a critical evolution, which should be viewed as a useful accompaniment for the analyzing, monitoring and reporting of adverse drug reactions (ADRs) and toxicity of herbal drugs. Quality control for efficacy and safety of herbal products is of utmost importance and debated issue in clinical practice. The assurance of the safety of a herbal drug requires monitoring of the quality of the finished product as well as the quality of the consumer information on the herbal remedy. Toxicovigilance is required for systematically identifying and correlating toxic substances and side effects and takes corrective actions. The aim of this communication is to promote the rationality of herbal medicine and to provide unbiased information regarding ADRs related to herbal products to entire healthcare society of world. It will also promote understanding, education and clinical training in toxicovigilance and its effective communication to the public.

References

1. http://www.who.int/ipcs/poisons/centre/toxicovigilance/en/.
2. Jacques D, Franc OT: Toxicovigilance: A new approach for the hazard identification and risk assessment of toxicants in human beings. Toxicology and Applied Pharmacology 2005; 207, 599 – 603.
3. Akerele O: Herbal Gram 1993, 28, 13.
4. Blumenthal M., Brusse WR. Goldberg A., Gruenwald J., Hall T., Riggins CW and Rister, RS : The Complete German Commission E Monographs. Therapeutic Guide to Herbal Medicines. The American Botanical Council 2005; Austin, TX, 1998.
5. WHO Guidelines on Good Agricultural and Collection Practices (GACP). World Health Organization, Geneva.
6. Gaedcke F., Steinhoff B: Herbal Medicinal Products. Scientific and Regulatory Basis for Development, Quality Assurance and Marketing Authorisation 2005. CRC Press, Boca Raton.
7. Ahmad FA; and M. Owais: Modern Phytomedicine. Turning Medicinal Plants into Drugs. Zeisel SH. Science 1999; 285, 1853. 144.
8. Petrovick PR., Marques LC., Paula IC: Alternative Health Care: The Canadian Directory. J . Ethnopharmacol 1999 ; 66, 51.
9. Pal SK., Shukla Y: Herbal medicine: current status and the future. Asian J. Cancer Prev, 2003; 4, 281.
10. WHO. General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine 2000; World Health Organization, Geneva.
11. Mukherjee PK., Verpoorte R: GMP for Botanicals: Regulatory and Quality Issues on Phytomedicines. Business Horizons, New Delhi. 2003.
12. Moore B., Adler R: Pediatrics. 2000, 106, 600.
13. McRae S: Herbal and Traditional Medicine: Molecular Aspects of Health. Can. Med. Assoc. J. 1996; 155, 293.
14. Desmet, P.A.G.M; Keller K., Hansel R., Chandler RF : Adverse Effects of Herbal Drugs. Springer-Verlag, Heidelberg 1997; 3,145.
15. http://faculty.ksu.edu.sa/23494/documents/quality%20control%20of%20herbal%20drugs.pdf .
16. Vikas D et al. Journal, Indian Academy of Clinical Medicine 2003; Vol. 4, No. 4, 345-347.