INTERNATIONAL JOURNAL OF CURRENT RESEARCH IN BIOLOGY AND MEDICINE
ISSN: 2455-944X
www.darshanpublishers.com
Volume 3, Issue 8 - 2018

Review Article

DOI: http://dx.doi.org/10.22192/ijcrbm.2018.03.08.002

Importance of Pharmacovigilance in Ayurvedha, Siddha, Unani (ASU) System of Medicines

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Abstract

Globally ASU formulations being widely accepted healing agents as antidiabetics, antiarthritics, hepatoprotectives, cough remedies and memory enhancers. The commonest myth regarding ASU medicines is that these medicines preferred by population, because they are natural. Moreover they are believed to be “safe” and “have fewer side effects” than “synthetic drugs” and can therefore be safely consumed by the patient on his/her own, without a physician’s prescription. This belief has led to large-scale self-medication by people all over the world, often leading to disappointing end-results, side-effects, or unwanted after-effects. There is an increasing awareness at several levels of the need to develop pharmacovigilance practices for ASU medicines. The current model of pharmacovigilance and its associated tools have been developed in relation to synthetic drugs, and applying these methods to monitoring the safety of ASU medicines presents unique challenges in addition to those described for conventional medicines. The main purpose of pharmacovigilance is to detect, assess, and understand, and to prevent the adverse effects or any other possible drug-related problems, related to herbal, traditional, and complementary medicines.

Keywords: ASU Medicines; Pharmacovigilance ; Adverse drug reaction.

Introduction

Pharmacovigilance is the science and activity relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products [(1)]. The word "pharmacovigilance" is derived from pharmakon (drug in Greek) and vigilare (keep an eye on/monitor in Latin). As such, It mainly focuses on adverse drug reactions (ADR), which are defined as any response to a drug which is noxious and unintended, including lack of efficacy. In this aspect, basically targets safety of medicine. Ultimately, It is mainly concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients [(2,3)]. World Health Organization (WHO), FDA (US Food and Drug Administration) and European Medicines Agency (EMA) introduced legislation on pharmacovigilance[(1,4,5)] to promote good vigilance practice standards with increased transparency of pharmacovigilance data; thus paving the way for pharmaco epidemiological studies[(6)].

Traditional Indian medicine has dated back to 3000 BC. One form of traditional Indian medicine is called Siddha, Ayurvedic and Unani. An example of the types of herbal products can be seen in Table. No: 1.Nearly all the traditional systems of medicine, the

medicinal plants play a major role and constitute their backbone. Adverse events may also result from the lack of knowledge of the wrong species of medicinal plants, incorrect dosing and errors in the use of herbal medicines by healthcare providers and consumers, interactions with other medicines and use of products contaminated with potentially hazardous substances such as toxic metals, pathogenic microorganisms and agrochemical residues.

Herbal medicines are widely available for purchase over the internet and from retail outlets in which there is no trained healthcare professional available (see section 1.3.1)[7]. Even where herbal medicinal products are purchased from pharmacies, a consumer or patient may not have any interaction with a pharmacist or trained pharmacy counter assistant or if a consultation does occur, pharmacy staff may not have sufficient knowledge to feel confident about providing information and advice on herbal medicines[8]. A related issue is that some users of herbal medicines may not disclose this use to a healthcare professional[9]; healthcare professionals do not ask their patients routinely whether they are using herbal medicines even when receiving reports from patients of suspected ADRs associated with conventional medicines and rarely record information on herbal-medicine use on patient records[10,11]. It is possible, therefore that undisclosed herbal-medicine use could be an alternative explanation for reports of suspected ADRs associated with conventional medicines.

Hence this attempt may help to document the possible ADR in herbal medicines particularly in ASU system of medicine and helps to prove our traditional medicine as safest medicine.

Table: 1. Medicinal Products from different sources:

Type of Herbal Medication	Natural Sources	Origins
Siddha	P, A, M	India
Ayurveda	P, A, M	India
Unani	P,A	India
Chinese	P, A, M	China
Indusynunic	P, A, M	Pakistan
Islamic	P, A, M	Middle East
Aromatherapy	P	European
Herbalism	P	European
Homeopathy	P	European
Botanicals	P	European

P: Plants; M: Minerals; A: Animal sources

In India, awareness and training programme are being conducted regarding adverse drug reactions related to Indian systems of medicine through National Pharmacovigilance programme. Considering the significance of drug safety, Ministry of AYUSH, Government of India launched the National Pharmacovigilance Programme for reporting the adverse drug reaction for Ayurveda, Siddha and Unani (ASU) drugs. A Protocol of National Pharmacovigilance Programme for ASU (NPP-ASU) drugs was published by Ministry of AYUSH, in collaboration with WHO, in order to have a proper documentation, to regulate, monitor and control the activities of Pharmacovigilance.

ASU Drugs and Possible Risk Factors:

In Indian systems of medicines, drugs are of herbal, mineral, metallic (particularly Arsenic, Mercurial derivatives) or animal origin. These drugs can also cause adverse drug events/reactions which are characteristic in nature to accompany the therapeutic efficacy of the drugs.

Need of Pharmacovigilance for AYUSH:

In this ASU system of medicine the minimum chance is there to develop Adverse Drug Event due to the following reasons,

- When improperly purified Poisonous herbs used in the traditional formulations
- Heavy metals particularly Arsenic and Mercurial derivatives are used for higher order medicine preparation
- When the Detoxification (Purification) procedure not performed for toxic ingredients before medicine preparation
- When the suitable time is not allowed for higher order medicine after its preparation
- When the dosage of medicine and the duration of medication period is not followed as recommended in the text
- When the higher order medicines administered in long time without any breaking period
- When the metallic preparations are administered without the suitable Adjuvant/ Vehicle

Recommendations:

There are several ways in which we can move forward in attempting to provoke pharmacovigilance in ASU systems.

- Introduce pharmacovigilance concepts into the ASU educational system.
- Make reporting of adverse reactions to regulatory mandatory for ASU formulations.
- Human resource development is a key feature for the success of this enterprise. It will be necessary to ASU experts in the science of pharmacovigilance and include them not only in reporting but also in assessment of the adverse reactions.
- Health care providers should remain vigilant for possible interactions between ingredients and prescription medications, especially for the medications having narrow therapeutic indices.

The safety and quality of herbal medicine in ASU system should be ensured through greater research, pharmacovigilance, greater regulatory control, and better communication between patients and health care providers. The recommended approach is to include traditional herbal medicines in existing National pharmacovigilance systems. In India Pharmacovigilance in herbal medicine is perhaps an unthought of concept as yet; we do not need “Herbal thalidomide” to wake the pharmacovigilance community to the need of the hour[12].

Conclusion

“ASU Pharmacovigilance” system needs to be established in order to assess the adverse effects that are caused by ASU products. For detecting the pharmacovigilance signals, information received from patients and healthcare providers plays a critical role in providing the necessary data. ASU Pharmaceutical Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations and guidance.

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How to cite this article:
Iyswarya. S, Visweswaran . S , Muthukumar. N.J , Banumathi. V. (2018). Importance of Pharmacovigilance in Ayurvedha, Siddha, Unani (ASU) System of Medicines. Int. J. Curr. Res. Biol. Med. 3(8): 6-9.
DOI: http://dx.doi.org/10.22192/ijcrbm.2018.03.08.002