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Pharmacovigilance -A Gateway to Safety and Efficacy of Ayurvedic Drugs

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Abstract

Pharmacovigilance is awareness towards adverse drug reactions. As per the guidelines of WHO to AYUSH department of Ministry of Health and Family Welfare; Government of India,implemented a pharmacovigilence program for Ayurveda, as a means to ensure the safety and efficacy of Ayurvedic medicines in year 2008. Continuing Medical Education and public meetings are being conducted to raise health professional's awareness of Ayurveda, Siddha and Unani drug. Main focus of pharmacovigilance is on adverse drug reactions (ADRs) and other medication errors to minimize the risk of harm associated with pharmaceutical products. Instead it was not familiar in ayurvedic texts, but the commercialization has brought with it many challenges about safe use of ayurvedic medicines, bringing into focus the need for formal pharmacovigilance programs in the field. Pharmacovigilance system depends entirely on the alertness of physicians towards ADRs. Several challenges that preclude identification and reporting of adverse reactions to ayurvedic drugs can be identified related to detection, assessment and prevention of adverse drug reactions. Awareness should increase about the science of pharmacovigilance among ayurvedic physicians, patients and paramedical staff. Attempt should be pointed towards collecting safety data during marketing of formulation. Safety monitoring of medicines in common use should be an integral part of clinical practice. With the help of modern informatics we can make an effective attempt in this area.

Keywords

Pharmacovigilance, Adverse drug reaction, ayurvedic drugs

INTRODUCTION

Pharmacovigilance is defined as 'the detection, assessment, understanding, and prevention of adverse effects of drugs or any other possible drug related problems'. This definition plainly covers the objectives of the AYUSH program and its coverage area as per the WHO guidelines [1] which is, monitoring and prevention of adverse effects with pharmaceutical products. To be specific, pharmacovigilance heavily focuses on adverse drug reactions (ADRs); which is defined as any response to a drug which is noxious and unintended, including lack of efficacy.

Adverse drug reactions occur at doses normally used for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. The activity that is most commonly associated with Pharmacovigilance is reporting of adverse event (AE) to the drug regulating authorities. AE refers to any injury occurring at the time a drug is used, whether or not it is identified as a cause of the injury. The source of AE reports may include spontaneous reports from healthcare professionals or patients (or other intermediaries), solicited reports from patient support programs, reports from clinical or postmarketing studies, reports from literature sources, reports from the media (including social media and websites); and reports reported to drug regulatory authorities themselves. For pharmaceutical companies, AE reporting is a regulatory requirement in most countries.

PHARMACOVIGILANCE IN AYURVEDA

Although the technical term "Pharmacovigilance" does not feature in ayurvedic texts, the spirit of pharmacovigilance is vibrant and is emphasized repeatedly in all major texts. The major goals of pharmacovigilance, namely to improve patient care and safety in relation to drug use, and thus promote rational drug use are recurrent themes of ayurvedic pharmacology and therapeutics [2]. The process of Pharmacovigilance is performed worldwide in conventional system of medicine (modern alias allopath) since more than half centuries to ensure safety and efficacy of different dosage forms of modern medicine. Certainly, there is pioneer contribution of this programme which has ascertained withdrawal of many molecules after reports of their adverse drug reactions through pharmacovigilance and post marketing surveillance. Encouraged by success of these programmes, World Health Organization convinced department of AYUSH of Government of India to bring Ayurvedic medicines under set up of surveillance for its monitoring on established parameters of safety and efficacy of a medicine through a Pharmacovigilance programme specially designed for Ayurvedic ,Siddha and Unani Medicines.

On 29 September, 2008 National Pharmacovigilance Programme for Ayurvedic Siddha and Unani Drugs was launched by central government recognizing Institute of Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurveda

University, Jamnagar as national resource centre for this programme.

AYURVEDA DRUGS NEED EFFICACY WITH SUPERIOR SAFETY

Though the traditional medical practices are deemed to be safest but sometimes adverse effects of these drugs are observed due to the non judicial use without the prescription, proper guidance and supervision of a qualified and registered medical practitioner of these systems of medicines. Ideally speaking, there should be a combined and integrative approach when evaluating efficacy and safety of a drug and due weight should be assigned to safety. The latter may be more important when confronting modest efficacy with superior safety. It is likely that in case of chronic diseases and long-term management (e.g., rheumatoid arthritis), physicians and patients may accept drugs with moderate efficacy but optimal safety. In order to make global acceptance the quality and its safety are under scrutiny though traditional practitioners prescribed them since long time. Bhasmas' a mineral preparation in Ayurveda, is prepared through special physico-chemical processes that, according to the ancient Indian belief, 'detoxify', toxic heavy metals in it. Strictly speaking, these constituents are thus not contaminants but ingredients deliberately included for a specific curative purpose. To promote its products in the international market, it is imperative to study their safety for human consumption.

ADVERSE DRUG REACTION IN AYURVEDA

According to drug and cosmetic act, 1940 the Ayurvedic drugs, which contain herbs like Ahipena (Papaver somniferurn Linn), Arka (Colotropis gigantean), Bhallataka (Semecarpus anacardium Linn. f.) Bhanga (Cannabis Sativa Linn.), Danti (Baliospermum montanum Mall. Arg.), Dhattura (Datura metal Linn.), Gunja (Abrus), Jaipala (Croton tiglium Linn.), Karaveera (Nerium indicum Mill.), Langali (Gloriosa superba Linn.), Parasilka Yavani (Hyocyamus inibar Linn.), Snuhi (Euphorbia neriifolia Linn.), Vatsanabha (Acontium chasmanthum), Vishmushti (Strychnox nuxvolnica Linn.), Shringivisha (Acontium chasmanthum) and the drugs which contain metals or minerals like Arsenic, Mercury, or Lead cannot be sold as OTC product. But due to lack of proper implementation of this law, many products are sold without prescription from a qualified Vaidya. Classical Ayurveda prescribes metals and minerals as medicines given as Bhasma (incinerated mineral formulations) in

combination with plants as herbo-mineral formulations (e.g., Aarogyavardhini). Manufacturing procedures for these medicines are stringent, and adverse reactions are described when precautions are not taken while manufacturing and administering these medicines [3]. Although these medicines are widely used in India, doubts about their long-term safety come up due to the presence of toxic metals in them [4] with reports related to adverse reactions [5]. Rasa Shastra products were more than twice as likely as non-Rasa Shastra products to contain metals, and several Rasa Shastra medicines manufactured in India could result in lead and/or mercury ingestion 100 to 10,000 times greater than acceptable limits.

AYURVEDA MEDICINE IN MIRROR OF PHARMACOVIGILANCE

In ancient times, the ayurvedic physicians prepared medicines for their patients themselves. Today, only a handful of practitioners follow this practice and production and sale of ayurvedic drugs has become formalized into a thriving industry. Manufacture and marketing of ayurvedic drugs is covered by the Drugs and Cosmetics Act, 1940[6]. Broadly speaking, two categories of medicines labeled as "Ayurvedic" are available in the market: firstly, classical ayurvedic formulations, which are, as per descriptions in ayurveda samhitas, *kutajarishta*, *chandraprabhavati*, etc.) and secondly patent and proprietary formulations made of extracts of herbs[7]. This commercialization has brought with it many challenges about safe use of ayurvedic medicines, bringing into focus the need for formal pharmacovigilance programs in the field.

The number of adverse reactions to ayurvedic drugs reported or recorded in the National Pharmacovigilance Program in India is negligible. The reason for this is the lack of knowledge about the concept and importance of pharmacovigilance in ayurveda among health care system.

REQUIRED ACTIONS FOR IMPLEMENTATION OF PHARMACOVIGILANCE PROGRAMME

1. Pharmacovigilance programme should come into curriculam of ayurveda.
2. Health practitioners should be aware of reporting the adverse reactions.
3. There should be a separate pharmacovigilance department in ayurveda

pharmacies and in ayurveda hospitals, under the control of pharmacovigilance experts.

4. Reporting of adverse reactions to regulators mandatory for ayurvedic formulations.

5. Development and validation of scales to assess the causality of the reported reactions to ayurvedic medicines.

6. Make unbiased and easily accessible drug information available. The Traditional Knowledge Digital Library launched by the Government of India [8] is an example of how ancient knowledge available in the ancient scriptures can be made digitally accessible.

7. Human resource development is a key feature for the success of this enterprise. It will be necessary to train ayurvedic experts in the science of Pharmacovigilance and include them not only in reporting but also assessment of the adverse reactions. More direct involvement of ayurvedic Academic Institutions in the NPVP after appropriate training would be an appropriate first step in this direction. A strong cooperative effort from experts in Pharmacovigilance and ayurveda together can ensure that this system is up and functioning. It is also possible that if we maintain safety parameters, then there will not be any ADRs/side effects in nature medicine.

CONCLUSION

All reported ADR were found to be preventable. ADR to ayurvedic medicines are generally mild in severity and preventable. Maximum number of ADRs in Ayurveda is of iatrogenic in origin rather than medicines. The other causes include irrational prescription, drug interaction, GMP concerns etc. If we are ware to these, it can be prevented.

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