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PHARMACOVIGILANCE IN *AYURVEDA* AND ADVERSE DRUG REACTION

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ABSTRACT

Pharmacovigilance is the science which encompasses the activities concerning the **detection, assessment, understanding, and prevention of Adverse Drug Reaction**. A common misconception prevails among the masses and also a large population of practitioners is that *Ayurveda* drugs are safe and do not have any adverse reactions. The major goals of pharmacovigilance, namely, to improve patient care and safety about drug use and thus promote rational drug use are recurrent themes of *Ayurvedic* pharmacology *Dravyaguna vigyana* (*Ayurvedic* pharmacology), and *Chikitsa* (therapeutics)[1]. Pharmacovigilance is an important tool to analyze the drug effect, particularly its side effects, if any. This paper outlines briefly the concept, the Need for Pharmacovigilance for *Ayurvedic* medicines, and implementation of the National Pharmacovigilance Program for *Ayurveda*, Siddha, Unani Drugs, Challenges in introducing PV in *Ayurveda*, and Recommendations.

Keywords: Pharmacovigilance, Adverse Drug Reaction, Side effects, Challenges.

INTRODUCTION

Ayurveda as a science has a vast history of research and development. The holistic approach of this ancient science envisions the prevention of disease,[2] under its basic principles of healthy lifestyle management, dietary intake, and the uniqueness of keeping in view the individual's physiology and mental state during treatment.[3]A lot has been said and discussed the effectiveness of one drug or the other in a wide spectrum of therapeutics but concerns regarding the safety and efficacy of these drugs have always been on the back seat. In the age of modern technology, scientific advancements, consumer awareness,

and the advent of evidence-based medicine, there is very sparse evidence supporting the efficacy and safety of *Ayurveda* drugs, except that this system is in practice for hundreds of years and there is rarely any adverse effect reported. Some time back serious concerns were raised about *Ayurveda* drugs that they contained heavy metals and were a threat to life.[4] It was only after that study, that the authorities in India initiated some concrete steps to regulate the drug industry more effectively.

Etymology: - Pharmaco – Drug**, Vigilance -** To be Awake/ Alert

Definition - It is the Pharmacologically related science related to the detection, collection, assessment, understanding, and prevention of adverse effects particularly long-term, and short-term side effects of Medicine.

Some Technical Terms Used –

ADR – Adverse Drug Reaction – A response to a drug that is noxious and unintended, and which occurs at doses normally used in man.

SE - Side Effect – Any unintended effect of a pharmacological product occurring at doses normally used in man.

SAE – Serious Adverse Event – Any fatal adverse event which is fatal, life-threatening, permanently disabling, or which results in hospitalization.

History-Thalidomide tragedy – 1961

Thalidomide is used in pregnant women to prevent nausea. It is a Potent human teratogen Caused major birth defects like Phocomelia (Absence of proximal part of limbs) in estimated 20,000 children.

Aim: -

- A patient care, public health & safety.
- Assessment of benefit, harm, effectiveness, and risk of medicine.
- Understanding, Education & Clinical training.

Objectives: -

- **Short-term objectives** – To develop the culture of notification.
- **Medium-term objectives** – To involve healthcare professionals & associations in the drug monitoring & information dissemination process.
- **Long-term objectives** – To achieve operational efficiencies that would make NPP for ASU drugs a benchmark for global drug marketing.

***Ayurvedic* concept of PV**

Pharmacovigilance means monitoring the effect of medicine after it has been licensed for use and administered for a particular condition. **Vigilance** means to be more careful, especially in order to notice possible danger or difficulties.

As per *Ayurveda*, any drug/management/procedure that, when administered, produces any untoward effect other than expected beneficial action is not considered a perfect treatment. Not only this, the **promotion of health and prevention of disease** is the first approach

in *Ayurveda*. Before starting any treatment, multifaceted analysis of the status of the patient is mandatory so

that the possibility of untoward symptoms due to error in diagnosis and planning of treatment is negligible.

A possibility to consider environmental factors along with psychological status further adds evidence that *Ayurveda* incorporates such concepts of being vigilant in the treatment. Instructions and guidelines in the form.

of ***Dashavidha Parikshya Bhava*** and ***Dashavidha Pariksha*** (tenfold examination along with the

consideration of ten factors to be examined before proceeding for treatment) indicate vigorous efforts to avoid errors in the diagnosis and management.

A list of **adverse drug events** may occur due to misuse of these preparations is elaborately along with probable **antidotes** and **precautions**. **Standard operating procedures** along with the implementation of the **Pre and Post -patient care** for ***Panchakarma*** procedures or para surgical interventions such as ***Rakta mokshana***, ***Agnikarma*,** and a vigilant approach for the management of possible complications can be also considered as a part of implementation of pharmacovigilance.

Not only this, for ***Shadvidha upakrama*** such as ***Langhana*** – Lightness/Deprivation, ***Brihmana*** - Nourishing, ***Snehana*** -Oleation, ***Rookshana*** -Drying,

Sthambana – Cooling, ***Swedana*** -Sweating, a strategy in the form of ***Samyak Lakshana*** has been mentioned with a warning that, if these procedures are not stopped after achieving the ***Samyak Lakshana***, adverse effects may be attained by the patient. Hence, guidelines along with medicines to be used for further possibilities are framed for such conditions.

Few factors may increase the chances of **Adverse Drug Reactions** (ADR) related to Ayurvedic medicines aggravate the **need for reporting,** such as the use of **substitute drugs** due to reduced availability of herbs, the emergence of new diseases and treatment modalities, and changing social structure and food habits, or chances of an irrational combination of medicines.

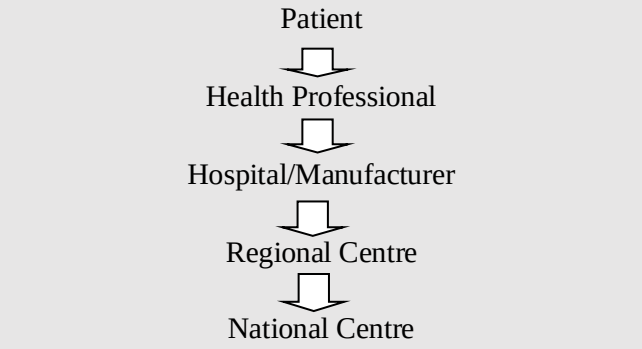
Term PV does not feature in *Ayurvedic* texts. Rational drug use is a recurrent theme of *Ayurvedic* pharmacology and therapeutics. Along with descriptions related to actions & benefits of medicine. ***Ayurvedic*** **pharmacology** describes detailed **adverse reactions** & also how to deal with ways to **minimize the adverse effect** in detail. On the other hand, the classical texts of *Ayurveda* promptly describe all the adverse reactions to irrationally procured, prepared, and administered drugs or formulations.

Initiatives taken by the Government of India for starting the National Resource Center for Pharmacovigilance is a beginning step for it. Pharmacovigilance in **India** was initiated way back in **1986** with a formal Adverse drug reaction (ADR) monitoring system, under the supervision of the drug controller of India. Later, the National Program of Pharmacovigilance was launched in **2005** and was renamed the **Pharmacovigilance Program of India (Pv PI) in 2010.**

PV CENTERS IN INDIA

- National -IPGT &RA Jamnagar
- Regional -8 centre's -B.H. U, Trivandrum, Guhati, NIA, CCRAS, Chennai, Bangalore, Bhopal
- Peripheral-30 centre's

Where to report?



What to report? All suspected adverse reactions, Lack of effects, Resistance, Drug interactions, and Reactions suspected of causing – Death, Hospitalization, Disability, and Congenital anomaly.

Who can report? Any health care professional may report suspected adverse drug events. The case reported by lay members of the public or non-health care professionals are not accepted under the program. But they can report the physician under whom they have undergone treatment.

Need for PV for *Ayurvedic* Medicines

In ancient times, physicians prepared medicines for their patients themselves. Today production and sale of *Ayurveda* drugs are formalized into a thriving industry.

Ayurvedic **medicines –**

1. Classical *Ayurvedic* formulations
2. Patent and proprietary formulations.

This industrialization has brought many challenges to the safe use of *Ayurvedic* medicines.

Challenges in introducing PV in *Ayurveda*: -

National Pharmacovigilance Program (NPP) encouraged reporting of all suspected ADRs, but number of reports related to *Ayurvedic* / herbal drugs is abnormally low. Concepts & terminologies related to ADR monitoring are not covered in the *Ayurvedic* curriculum. Methods to study drug safety problems have not evolved adequately in *Ayurveda*. Information related to medicines is in the form of *slokas* in the texts, it is not easily available to the general public. Signal detection is difficult because of the inherent belief that *Ayurvedic* medicines are safe. Patients often use medicines from different systems of medicine concomitantly - difficulty in assigning causality. Lack of qual-

ity assurance and control in the manufacture of *Ayurvedic* medicine. Most *Ayurvedic* formulations are multi-ingredient.

Recommendations: -

Introduce pharmacovigilance concepts into the curriculum of *Ayurveda* at the under-graduate and post-graduate levels. Encourage studies on drug safety. Make reporting of adverse reactions to regulators mandatory for ayurvedic formulations. Make unbiased and easily accessible drug information available. Create awareness about the science of pharmacovigilance among *Ayurvedic* physicians, patients, and paramedical staff.

DISCUSSION

A general misconception that prevails among the common people is that *Ayurveda* medicines are always safe. This mindset needs to be changed. Though these medicines are safer, their intake of being immune from any side effects is not the case. If a drug is not manufactured as per set protocols or if any incompatible (*viruddha*) intake is done and then side effects are bound to occur. The Department of AYUSH has gone a long way in creating infrastructure for pharmacovigilance reporting. Though this is still in its infancy, we should strengthen the basic idea which has led us to think and discuss this issue. The clinicians of *Ayurveda* should be given training regarding the assessment of adverse reactions and must be taught the procedure for reporting such reactions. The forms for assessing and reporting should be simplified to facilitate easy reporting. Close monitoring of all drug prescriptions should be done. Adequate inclusion of pharmacovigilance may be done in the undergraduate curriculum of *Ayurveda*. Prescription of *Ayurveda* drugs along with modern drugs should be avoided so that the effect of drugs on the human body can be analyzed. Bulk dispensing of drugs is a major issue and steps should be taken to monitor it. Dispensing of *Churna* (powders) in sachets can be done to provide a fixed-dose. Similarly, *Bhasma* can be dispensed in capsule forms. Pharmaceutical houses need to share the burden and as well as responsibility for the proper implementation of the pharmacovigilance program. Data generated from various studies like clinical or pharmacological trials should be regularly updated in the textbooks. Experts of *Ayurveda* may also be reoriented and trained as experts in pharmaco-vigilance. The drug information should be easily available and should be completely digitalized so that the knowledge is available instantly. Though, the Traditional Knowledge Digital Library is a positive step in this direction.

CONCLUSION

By implementing the Pharmacovigilance and taking the appropriate measures right from the collection of raw materials, preparation of drugs, clinical trials for new formulations, awareness of the products, long term, and short-term adverse effects, data collection of benefits and risks from the subject experts, health care providers, patients and analyzing them by utilizing digital technology adds benefit to the society for attaining timely and fruitful results.

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