



IMPORTANCE OF PHARMACOVIGILANCE IN AYURVEDA

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ABSTRACT

Ayurveda is a science of life and the basic motive of the Ayurveda is to promote the health of healthy persons and cure the diseases of the diseased persons. In Ayurveda we use many kind of medicines like *Kastha aushadhi* means medicines which prepared by plants origin and *Rasa aushadhi* means medicines which prepared by metals and submetals. A general misconceptions present in our society that the ayurvedic medicines are safe and do not have any side effects, so people takes ayurvedic medicines without consulting the physician. Although the ayurvedic medicines are safe, no doubt but it depends upon the method of administrations. Ayurvedic medicines have different kind of pharmacology. The action of drugs depends upon the humans *Shareerik prakriti* (i.e *Vata, Pita, Kapha*) *Agnibala, kala, Satva* etc. If we ignore these all factors definitely the drug shows his side effects. Many pharmaceutical industries ignores important steps in drug manufacturing such as the quality of raw material, ratio in combinations of drugs used in medicines and purity of medicines after manufacturing. These factors reduce the efficacy of drugs and many times it is dangerous to take because if impurities are presents in any medication it shows dangerous side effects and can be fatal for human health. Pharmacovigilance is the science which deals with the Detection, Assessment, Understanding and prevention of unintended effects, side effects of drugs or any other medication error. In this research paper we discussed about importance of pharmacovigilance in ayurveda and its role in public health and safety.

KEYWORDS: Pharmcovigilance, side effect.

INTRODUCTION

Pharmacovigilance is the pharmacological field which deals with the Detection, Assessment, Understanding and Prevention of unintended effects, adverse drug side effect or any other possible Medication error, caused by pharmaceutical product. Pharmacovigilance promotes the systemic, rational use and assures the confidence for the safety of drugs. It improves patient care and safety, public health and safety. Although the technical term Pharmacovigilance does not mentioned in Ayurvedic text, the spirit of pharmacovigilance is vibrant and is emphasized repeatedly in *Brihatrayee* and *Laghutrayee*. There is a common perception of people about Ayurvedic medicine that these medicines have no adverse reactions, but it is clearly mentioned in Charak Samhita that the most useful drug can act like a poison if handled carelessly. On other hand a strong poison can become an excellent medicine if administered properly.^[1]

AIMS AND OBJECTIVES

The main objectives of this research paper is explain what are the Ayurvedic concepts related to the side

effects to medicines, which factors affect the efficacy of the medicines and how to improve public health and safety in relation to use of medicines.

MATERIALS AND METHODS

A detail study will be done from the *Brihatrayee* and date available from researches, journals and resources.

HISTORICAL BACKGROUND OF PHARMACOVIGILANCE IN INDIA

Pharmacovigilance was established since 2003 under the control of Central Drug Standard Control Association (CDSCO) under the aegis of Ministry of H & FW, DGHS(Directorate General of Health service) New Delhi.

WHO emphasized that it should include Traditional medicines in Pharmacovigilance system and has published guidelines on safety monitoring of herbal medicines in pharmacovigilance systems in 2004.

IPGT & RA, Jamnagar conducted a two days workshop on 3rd & 4th December 2007, on “Pharmacovigilance for Ayurvedic Drugs: Scope, Limitations & Methods of Implimentation”. Based on the recommendations from the workshop, pharmacovigilance cell (PV Cell), has been stabilished. Reporting from for suspected ADR’s of Ayurvedic Formulations has been developed.

The first National Consultative meet of National Pharmacovigilance Programme for ASU Drugs was organized at Dept. of AYUSH, Ministry of Health & FW, New Delhi on August 2008, sponsored by WHO. Based on the feedback received from the meet, National Pharmacovigilance Programme for ASU drugs was launched on 29th Sept 2008.

AYURVEDIC CONCEPTS OF DRUG ACTIONS

In the modern pharmacology the drug actions is often correlated with its chemical structure and active principle. However, in Ayurvedic pharmacology the drug action is depends upon active principle of drug such as *Rasa, Guna, Virya, Vipaka and Prabhava*. These five basic principles are known as *Rasa-Panchak*. In Ayurveda in relation to pharmacodynamics, the properties of drugs have been described in terms of *Ras-Panchaka*. Ayurvedic medicines are analyzed on the basis of their stable tastes (*Rasa*), efficacy (*Virya*), physical properties (*Guna*), unstable taste (*Vipaka*) and unique powers (*Prabhava*). Acharya charak described in samhita that some drugs works by *Rasa*, some by *Guna*, some with *Virya*, some with *Vipaka* and some with *Prabhava*.^[2]

AYURVEDIC CONCEPTS OF SIDE EFFECTS

There is a major misconception among masses and also a large population of practitioners that Ayurvedic drugs are safe and do not have any side effects. Ancient texts clearly mention that if a drug is used without the knowledge of its proper action, it would certainly act as a poison. Attention is given to factors like the physical appearance of the part of the plant to be used (*Prayojyang*), its properties (*Guna*), action (*Karma, Prabhava*), habitat (*Desh*), season in which it grows (*Ritu*), harvesting conditions (*Grahitam*), method of storage (*Nihitam*) and pharmaceutical processing (*Upaskritam*), which must be considered while selecting the starting material that goes to form the medicines.^[3] The decision making regarding prescriptions of a drug also relies upon the *Yukti* of the physician and his minute assessment of the *roga* and *rogi bala*, the time of administration of drug (*Kala*), its place (*Desh*), physiological state (*Satva*), tolerance (*Satmya*), digestive capacity (*Ahara Sakti*), capacity for exercise (*Vyayama Sakti*).^[4] Besides the knowledge of proper identification of drug, its properties, therapeutic dosage and its combination with other drugs some of the subjective tools and crude principle of pharmacovigilance used since ancient time to keep ADR’s of Ayurvedic medicines. Ayurveda proves its worth to the modern world. Practice of pharmacovigilance will compel us to

strive harder to make more safer and authentic medicines and make Ayurveda more rational and reliable.

NEED OF PHARMACOVIGILANCE IN AYURVEDA

- This is a myth present in the society that Ayurvedic drugs do not have side effect. This fact simply understands by food.
- To promote understanding, education and clinical training in pharmacovigilance and its effective communication to health professionals and the public.
- To improve public health and safety in relation to the use of medicines.

DIFFICULTY IN SUCCESSFUL IMPLEMENTATION OF PHARMACOVIGILANCE IN AYURVEDA

- No reporting of ADR’s.
- Generally physicians ignore ADR’s.
- False belief about the universal safety of Ayurvedic drugs.^[5]
- It is difficult to monitor multiple ingredient formulations.
- Most of the physicians prescribed herbal and allopathic drugs together.
- Concept related to adverse reactions not covered in under graduation and post graduation syllabus.
- Poor patient compliance and ignorance, apart from selfmedicational and home remedies that are practised by many people.
- Non-availability of collection of ADR’s for Ayurvedic medicines.
- Less awareness about pharmacovigilance in ayurveda.

RECOMMENDATIONS

Based on these observations there are several methods by which can be include pharmacovigilance into Ayurvedic system of medicines

- Introduce pharmacovigilance concept into the syllabus of ayurveda at the under-graduate and post-graduate level.
- Promot studies on drug safety.
- Make reporting of adverse reactions for ayurvedic formulation is mandatory.
- Creat awareness about the science of pharmacovigilance among ayurvedic physicians, patients and paramedical staff.
- Development and validation of scales to decied the causality of the reported reactions of ayurvedic medicines.
- 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.^[6]

DISCUSSION

Commonly a large population thinks that Ayurvedic medicines do not have any side effects and people thinks it's always safe. It is necessary to change this mind set. The practitioner of Ayurveda should be given training regarding assessment of side effect and must be taught the procedure for reporting of such side effects. Student should be educated at the graduate and post graduate level. Monitoring the side effects of drugs should be done by the physician at the OPD level and pharmaceutical industries by the clinical trials.

CONCLUSION

The need of the present era is to educate the physicians and encourage them to analyse and report any adverse effects that occur in a patient. Quality drugs are one of the main pillars of effective therapy. The industry should take some strong steps to generate confidence and reliability for its products. The morality of manufacturing standard drugs can go a long way in minimizing the adverse effects and generating confidence in therapeutic efficacy. This shall only be a step towards global acceptance of Ayurvedic drugs.

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