

RELEVANCE OF PHARMACOVIGILANCE WITH REFERANCE TO HERBAL DRUGS

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ABSTRACT

It is a well-known concept with herbal drugs that these are innocent and time tested thus does not cause any "Adverse Drug Reaction". While there are well documented side effects with modern or Allopathic drugs. In the oldest treatise of *Ayurveda* "*Charak Samhita*" it is mentioned that an ideal treatment not only cures the diseases but not cause other ailments.¹ Therefore from the ancient times it was tried in *Ayurvedic* system of medicine to minimize the side effects. For this purpose many procedures have been followed to make a finish product without any adverse effect. Moreover side effects or contraindications of drugs have been clearly documented in different texts. In the present paper these documented side effects with certain herbal drugs are defined and elaborated in present context.

Keywords: *Pharmacovigilance, Adverse Drug Reaction, Treatise.*

INTRODUCTION

According to WHO, 3 Billion people in developing countries (80% of population), and one billion in western countries (30-50% of population) use traditional medicine. In India, out of 15000 plant species available about 2000 species used as medicinal plants.² According to WHO, Pharmacovigilance is defined as the detection, assessment and prevention of adverse reactions to medicinal products in humans.³ Adverse effect is any undesirable effect or unwanted consequences of drug administration.

Adverse effects may be divided into two types;

- Type1 or Predictable type.
- Type 2 or unpredictable type.

Drugs of *Ayurvedic* system of medicine are of two main types. A) Herbal mixture of

plants and animal products. B) Herbomineral- Mineral and plant and animal products. Therefore herbal part is almost the most common ingredient of *Ayurvedic* formulations. Hence every *Ayurvedic* physician should aware of the documented side effects of these herbs. The side effects or ADR with these herbs are presented here. Some of the herbs which are selected here are; **Guggulu, Lasuna, Ghrtkumari, and Vacha.**

Documented ADR with Guggulu:

Guggulu or *Commiphora wightii* is a very useful drug of Indian system of medicine.

Guggulu: In Indian system of medicine *Guggulu*(*Commiphora wightii* Arnott Bhandari) is a well-known drug in *Ayurvedic* system of medicine .It is the drug of choice for inflammatory and nervine disor-

ders^{1,4,5}. (*guggulu medoanil haranam*) Its antiobesity and hypolipaeidemic role is well established since the time immemorial^{4,5}. It has been mentioned in *Ayurvedic* texts that new or fresh *guggulu* should be used for rejuvenating and strengthening of body while old one cause excessive leaning (*lekhana*)^{4,5}. Therefore effect of both types of *guggulu* is opposite and should be used as per requirement of the patient.

Contraindications during guggulu therapy

One who is on *guggulu* therapy should completely restrict the sour and heavy food, coitus, vigorous physical activities, exposure to Sun, and liquor and aggressive behaviour⁵. Its intake is contraindicated in old age, pregnancy, and puerparium⁶. Some studies reveals that it can cause urticaria and kidney disorders⁵. The old *guggulu* is documented as spermicidal^{4,5}, therefore should not use in young men.

Overdose: Its overdose can cause damage to liver and lungs.⁷ In *Ayurvedic* treatise it is documented as '*Gunanidhi* 'if used in proper dose. Overdose can cause blindness, dryness of mouth, impotency, weakness, dryness of body and coma. Moreover its use is contraindicated in above mentioned diseases⁸.

Documented ADR with *Rasona* (*Allium sativum* Linn.)

Rasona: *Rasona* or *Lashuna* is the one of the most popular herb used in traditional system of medicine as well as home remedy for various disorders. It is found very useful in *vatika gulma* and *udaverta*^{1,9}. Clinical studies also proved its role in epigastric and abdominal distress, belching, flatulence, colic and nausea¹⁰. Garlic also having lipid lowering¹⁰ and fibrinolytic, anti-coagulant activity¹¹. *Maharshi Kashyapa* narrated its importance in *Lashuna kalpa*¹².

Contraindications of *Lashuna* (*Allium sativum* L.)

Lashuna is contraindicated in *Pattika* diseases, *pittaraktavrita vata*¹². It is also contraindicated during decay of body, old age, fever, pureparium, pregnancy and in children, diarrhoea, jaundice, piles, constipation, throat and oral cavity diseases, at the time of vomiting, hiccough and asthamic cavity¹². In present context it should be contraindicated in Dengue fever, Haemophilia, disfunctional uterine bleeding, epistaxis, bleeding piles, and during coagulant therapy.

Documented ADR with *Ghrtkumari* (*Aloe barbadensis* Mill.)

Ghrtkumari: The most popular herb used as home remedy due to its easy availability and and cultivation. It is very effective remedy in *Agnidagdha* (burns), *Rajorodha* (Amenorrhoea), *Pliharoga* (spenic disease), *Ykrtvridhi* (hepatomegaly), *Raktapitta* etc⁵.

Containdication of *Ghrtkumari:* *Ghrtkumari* is contraindicated for the patients of Piles, uterine prolapse, Meno-metrorrhgia and renal diseases¹³.

Documented ADR with *Vacha* (*Acorus calamus* Linn.)

Vacha: It is ideally used in mental disorders like Epilepsy, Dementia, Hysteria, correction of speech in children^{4,5,7}. It is also used for rejuvenating therapy⁴ and germicidal purpose⁶. its therapeutic dose is 125 mg./day.

Overdose of *Vacha*

Overdose even at 1 gm./day can cause excessive vomiting. It slows the heart rate and lowers the bloodpressure⁷.

CONCLUSION

In this paper it was concluded that in *ayurvedic* system of medicine effect and side effects are well documented. We don't claim

that all herbal drugs are always harmless. Herbal drugs also need caution and the side effects of these drugs should be well In knowledge of physician as well as patients. Therefore some suggestions are given here:

1. Manufacturers should attach a leaflet containing medical conditions where drugs are contained.
2. Safety and effectiveness of the drug in children, pregnancy, and geriatric.
3. A rational analysis and research on the prospects of various types of herbal adverse effects should be carried out.

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