RELEVANCE OF PHARMACOVIGILANCE WITH REFERANCE TO HERBAL DRUGS

Neelima Sharma¹  Umesh C. Sharma² Madhu singh³
1. Research Officer Ayurveda Nvari Jhansi, Uttar Pradesh, India
2. Assistant professor, department of Shalya Tantra, 3. Assistant professor, department of Rog vikrti. Bundelkhand Govt Ayurvedic college Jhansi, Uttar Pradesh, India

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 nerve disor-
ders1,4,5 (guggulu medoanil haranam) Its antiobesity and hypolipaidemic role is well established since the time immemorial4,5. It has been mentioned in Ayurvedic texts that new or fresh guggulu should be used for rejuvinating 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 spermicidal4,5, therefore should not use in young men.

Overdose: Its overdose can cause damage to liver and lungs7. In Ayurvedic treatise it is documented as ‘Gumanidhi ‘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 L.)

Rasona: Rasona or Lashuna is the one of the most populer herb used in traditional system of medicine as well as home remedy for various disorders. It is found very useful in vatika gulma and udaverta1,9. Clinical studies also prooved 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 kalpa12.

Contraindications of Lashuna (Allium sativum L.)

Lashuna is contraindicated in Pattika diseases, pittaraktavrita vata12. 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 asthamatic 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 populer herb used as home remedy due to its easy availability and cultivation. It is very effective remedy in Agnidagdha (burns), Rajorodha (Amenorrhea), Pliharoga (spenic disease), Ykrtvridhi (hepatomegaly), Raktapitta etc5.

Contraindication of Ghrtkumari: Ghrtkumari is contraindicated for the patients of Piles, uterine prolapse, Menometrorrhgia 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 children4,5,7. 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 known to the physician as well as patients. Therefore some suggestions are given here:
1. Manufacturers should attach a leaflet containing medical conditions where drugs are contraindicated.
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.

REFERENCES
1. Pandey Kashinath and Chaturvedi Gorakhnath Vidhotini Hindi Commentary on Charak samhita, Chaukhambha Vishwabharati publication, 1998 Ed.
2. WHO-General guidelines for methodologies on Research and evaluation on traditional medicine 2001.
3. Guidelines for the regulation of herbal medicines in South-East Asia, WHO Regional office for South East Asia, New Delhi.
8. Anant Damoder Athavale, Ashtanga Sangraha of Vrdda Vagbhata Pub. Ma-

heshya Ananta Athvale. Naandnandan, Pune; Shridam Atreya prakashan; 1980.

CORRESPONDING AUTHOR
Dr. Neelima Sharma
Research Officer Ayurveda NVARI
Jhansi, Uttar Pradesh, India
Email: dneelimasharmayu@gmail.com

Source of support: Nil
Conflict of interest: None Declared