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Adverse Effect of Herbal Medicines: Myth versus Reality

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Medicinal plants sector has traditionally occupied an important position in the socio-cultural, spiritual and medicinal arena of rural and tribal lives of India. The rural people constituting about 70 to 75% of the Indian populations live in about 5,76,000 villages located in different agroclimatic conditions use herbal medicines extensively due to increased availability and low cost [1].

In the last decade, herbal medicine has revived and advanced at a greater pace with wide community acceptance for their therapeutics effects. This field is bringing forward new lead drug discoveries as well as safe and efficacious plant-based medicines [2]. Large numbers of pharmaceutical companies are now involved in the research and development of plants as a source for modern medicine. Most of the herbal medicines are sold as over-the-counter (OTC) products or directly dispensed by traditional healers. Some of the herbal formulations adheres to scientific methodology and have been generated based on reasonably sound data whereas most of them are prepared by unregistered manufacturers without license do not follow the Good Manufacturing Practice (GMP) or Indian System of Medicines (ISM) standards [3].

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There is a predominant myth in society that medicinal herbs or plants are much safer than conventional pharmaceuticals due to its "natural" origin. Unfortunately, this is not the truth! Like all other medicines, to be efficacious there is a specific dosage threshold for herbal medicine also, as well as to be toxic. Literature reports that many herbal medicine preparations are potentially toxic and some are even carcinogenic [2]. For example, aristolochic acid derived from *Aristolochia* species; Anthranoid laxatives from aloe, cascara, rhubarb and senna; and Chaparrel (*Larrea tridentata*) have genotoxic and mutagenic potential is associated with the development of cancer [4]. Popularly used herbs like Ginseng (*Panax ginseng*, *Panax quinquefolius*) and St. John's Wort (*Hypericum perforatum*) can increase blood pressure rapidly. Ginko (*Ginkgo biloba*), Garlic (*Allium sativum*), ginger (*Zingiber officinale*), and capsicum (*Capsicum annuum*) can potentially interfere with blood coagulation mechanism [5]. Most of the OTC herbal medicines are not supported by proper scientific evidence in terms of efficacy and safety. The lack of proper standardization and the use of multi-herbs in a single prescription massively increase the safety risk. Not only the multiple phytochemicals in polyherbal preparations can cause synergism, antagonism, drug-herb or herb-food interaction but can also cause toxicity due to heavy metals, microbial contamination, aflatoxin and other chemical contaminants [6]. Presence of excessive or banned pesticides, heavy metals and microbial contaminants are may be related to the source of these herbal materials, if they are grown under contaminated environment or during collection of these in plant materials. The commonly contamination dangerous heavy metals are mercury, arsenic, lead and zinc [7]. Microbial contaminants are *Bacillus cereus*, *Aeromonas hydrophilia*, *Shigella* spp., *Enterobacter agglomerans*, *Enterobacter* spp., *Vibrio fluvialis*, *Escherichia coli* and *Klebsiella*. Common fungi are *Aspergillus* species [8]. Aflatoxins are a group of mycotoxins produced by

Aspergillus species, including *A. flavus*, *A. parasiticus*, and *A. nomius*. Aflatoxin B1, B2, G1 and G2 are the most important members of the aflatoxin group, which chemically are coumarin derivatives with a fused dihydrofurofuran moiety. Aflatoxins are associated with both acute and chronic toxicity in animals and humans including acute liver damage, liver cirrhosis, and liver cancers [9].

Toxicity of herbal medicines is often caused by heavy metal contamination also. Herbal medicine can be a boon to human kind as far as we use it rationally and follow all safety standards. The toxic effect of herbal medicines mostly occurs due to existence of potent phytotoxins in some plants, mistakes in botanical identification, contraindicated combinations of plants, pharmacokinetic interaction with allopathic drugs when used with conventional pharmacotherapy and poor quantification of dose [10].

The Indian Government has recognized the need of adopting astringent guidelines for the manufacturing and sale of traditional medicine. The Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) and ISM along with Food and Drug Administration has taken steps to protect the health of consumers by implementing the 'Good Manufacturing Practices for Ayurveda, Siddha and Unani Medicine's as Schedule T of Drugs and Cosmetics Rules 1945. Herbal medicine products must be registered and their advertisement scripts should approved by regulatory bodies prior to their marketing. Labeling of herbal medicines should also be controlled strictly banning them to claim unauthorized properties, which misguide the general public and provoke them to use without need or without the consent of a practitioner.

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Authors Column

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