

SAFETY CONCERNS IN AYURVEDA – A SYSTEMATIC REVIEW OF CAUSES AND PREVENTIVE STRATEGIES FOR ADVERSE DRUG REACTIONS.

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ABSTRACT

Ayurveda, one of the world's oldest traditional medical systems, is widely practised and increasingly integrated into modern healthcare frameworks. While it is often perceived as inherently safe due to its natural origins, recent evidence highlights the occurrence of adverse drug reactions (ADRs) associated with Ayurvedic medicines.

This systematic review aims to critically examine the underlying causes of ADRs in *Ayurvedic* practice and propose effective preventive strategies. The review identifies multiple causative factors, including contamination with heavy metals, improper prescribing practices, lack of standardisation, herb-drug interactions, and patient-related variables such as self-medication. Notable ADRs include hepatotoxicity, nephrotoxicity, and allergic reactions linked to commonly used formulations. Preventive measures such as stringent regulatory oversight, pharmacovigilance systems, practitioner training, product standardisation, and public awareness are discussed. Strengthening these areas is critical to ensuring the safe use of Ayurvedic medicine and promoting evidence-based integration with conventional healthcare. To address safety concerns and improve pharmacovigilance in traditional medicine systems, the Ministry of AYUSH, Government of India, launched the Ayush Suraksha program. It is a national initiative aimed at detecting, assessing, and preventing adverse drug reactions (ADRs) and misleading advertisements related to *Ayurveda*, Siddha, Unani, and Homoeopathy (ASU&H) drugs.

Keywords: *Ayurveda*, Adverse Drug Reactions (ADRs), Herbal Medicine Safety, Pharmacovigilance, Heavy Metal Toxicity, Traditional Medicine, *Ayurvedic* Regulation, Herb-Drug Interactions, GMP, Integrative Medicine, Ayush Suraksha.

INTRODUCTION

Ayurveda, an ancient form of medicine that originated in India over 3,000 years ago, promotes a holistic approach to health and wellness based on the balance of physiological energies (*Vata*, *Pitta*, and *Kapha*). *Ayurveda* includes the use of natural substances such as herbs, minerals, and animal products, which are frequently adapted to an individual's constitution (*Prakriti*). While *Ayurvedic* medicines are typically considered safe due to their natural origin, they are not exempt from adverse drug reactions (ADRs). ADRs in *Ayurveda* may arise from faulty formulation, inappropriate dosage, contamination, or individual intolerance to specific ingredients.

A study showed that 142 adverse drug events were reported during a period of two years (April 2020 to

April 2022), with 17 of these being identified as ADR related to suspected *Ayurvedic* medications. One adverse reaction was reported with *Chyavanprash*, five with homemade decoction, and one with *Ayush kwath*. Two ADRs were recorded from *yashtimadhu churna*.^[1]

Another article reported that the patient developed reddish rashes and itching over the area treated with *Kottamchukkadi churna lepa*.^[2]

A patient taking *Tribhuvan kirti rasa* along with *Sanjivani vati* developed severe prostration, vomiting and headache due to overdose of *vatsnabh*.^[3]

PREDICTABLE ADVERSE REACTION OF METALLIC BHASMAS USED IN AYURVEDA ^[4]

METALLIC PREPARATION	INDICATION & PHARMACOLOGICAL ACTION	HARMFUL IMPACT (WITHOUT SODHANA AND MARANA)
<i>Parada</i> (Mercury, Hg)	In all the diseases with a specific <i>Anupana</i> (adjuvant) as required	<i>Murcha</i> (fainting), <i>Chhardi</i> (vomiting), <i>Atisara</i> (diarrhoea), <i>Shwasa</i> (dyspnoea), etc., and even death.
<i>Swarna</i> (Gold, Au).	<i>Kshaya</i> (emaciation), <i>Shwasa</i> (dyspnoea), <i>Kasa</i> (cough), <i>Pandu</i> (anaemia), <i>Hridya</i> (cardiac tonic), <i>Rasayana</i> (immune modulator), <i>bala bardhaka</i> , <i>vajikar</i> , etc.	Reducing <i>Ojus</i> and <i>Bala</i> (defence mechanisms) can lead to many other diseases, even death.
<i>Rajata</i> (Silver, Ag)	<i>Madatyaya</i> (alcohol dependence), <i>Kshaya</i> (emaciation), <i>Plihodara</i> (splenomegaly), <i>Apasmara</i> (epilepsy), etc.	<i>Jvara</i> (fever), <i>Vibandha</i> (constipation), <i>Angasada</i> (fatigue), etc.
<i>Tamra</i> (Copper, Cu)	<i>Pandu</i> (anaemia), <i>Krimi</i> (warm infestation), <i>Sthaulya</i> (obesity), <i>Kustha</i> (skin disorders), etc.	<i>Vamana</i> (vomiting), <i>Shula</i> (spasmodic pain), <i>Kustha</i> (skin disorders), etc., and even death.
<i>Lauha</i> (Iron, Fe)	<i>Pandu</i> (anaemia), <i>Shotha</i> (oedema), <i>Rajyakshma</i> (tuberculosis), <i>Kustha</i> (skin disorders), <i>Rasayana</i> (immunomodulator), etc	<i>Hritpida</i> (angina), <i>Ashmari</i> (urolithiasis), <i>Apasmara</i> (epilepsy), <i>Shotha</i> (oedema), <i>Shula</i> (abdominal colic), etc.
<i>Vanga</i> (Tin, Sn)	<i>Krimi</i> (warm infestation), <i>Vamana</i> (vomiting), <i>Kasa</i> (cough), <i>Shwasa</i> (dyspnoea), <i>Pandu</i> (anaemia), <i>Prameha</i> (diabetes mellitus), <i>soma roga</i> , etc.	<i>Prameha</i> (diabetes mellitus), <i>Kasa</i> (cough), <i>Shwasa</i> (dyspnoea), <i>Pandu</i> (anaemia), <i>Shotha</i> (oedema), etc
<i>Naga</i> (Lead, Pb)	<i>Prameha</i> (diabetes mellitus), <i>Arsha</i> (piles),	<i>Murcha</i> (fainting), nephrotoxicity,

	<i>Vrana</i> (ulcer), <i>Pradara</i> (leucorrhoea), <i>Sukrakshaya</i> (oligospermia), etc.	<i>Pakshavadha</i> (paralysis), <i>Shotha</i> (oedema), etc.
<i>Yasada</i> (Zinc, Zn)	<i>Prameha</i> (diabetes mellitus), <i>Pandu</i> (anaemia), <i>Shwasa</i> (dyspnoea), <i>Netraroga</i> (eye diseases), <i>Vrana</i> (ulcer), etc.	<i>Prameha</i> (diabetes mellitus), <i>Kshaya</i> (emaciation), <i>Vamana</i> (vomiting), <i>Kustha</i> (skin disorders), etc.

PREDICTABLE ADVERSE REACTION OF POISONOUS MEDICINAL PLANTS USED IN AYURVEDA^[5] -

MEDICINAL PLANT	INDICATION & ACTION	SIDE EFFECT
<i>Ahiphena</i> [Papaver somniferum]	<i>Atisara</i> (Diarrhoea), <i>kasa</i> (Cough and bronchitis), <i>jvara</i> (Fever), <i>shoola</i> (Pain), <i>Nidranasa</i> (sleep disorder), and Erectile dysfunction.	Constipation, irregular bowel movement, Nausea and vomiting.
<i>Arka</i> [Calotropis procera]	Improve digestion, increase gastric motility, anti-inflammatory, wound-healing, beneficial for skin, splenic disorders, and worm infestation.	Diarrhoea and vomiting.
<i>Bhallataka</i> [Semecarpus anacardium]	All <i>kapha</i> roga, constipation, <i>Arsha</i> (haemorrhoid), and skin diseases.	Produce skin rash and blister.
<i>Bhanga</i> [Cannabis sativa]	Digestives induce sleep, constipation, obesity, increase libido, anorexia, IBS, <i>Shoola</i> (Pain), <i>Rasayana</i> .	<i>Madakari</i> (Intoxication): Increase the urge to speak.
<i>Chitraka</i> [Plumbago zeylanica]	Digestive, appetiser, worm infestation, cough and cold, IBS, Piles <i>Shoola</i> (Pain), hepatomegaly.	Gastritis and neuropathy may induce menstrual bleeding and a burning sensation.
<i>Dhatura</i> [Datura metel]	Asthma, fever, External application to the skin and musculoskeletal disorders.	Headache, convulsion, Hallucination.
<i>Gunja</i> [Abrus precatorious]	Aphrodisiac, hair tonic, good for the eyes, and increase immunity.	Vomiting and purgation.
<i>Jayapal</i> [Croton tiglium]	Alopecia, induced purgation, cough, chronic constipation, asthma, and snake bite.	Purgation, burning sensation, vomiting, and electrolyte imbalance.
<i>Karavira</i> [Nerium indicum]	Chronic wound healing, external application in fistula, boil, and pain management.	Cardio-toxic
<i>Langali</i> [Gloriosa superba]	Useful in gout, scorpion bite, external application in lice, and induces abortion.	Abortifacient, diarrhoea, vomiting.
<i>Vatsanabha</i> [Aconitum ferox]	Fever, pain, <i>amapachaka</i> (detoxifier)	Vertigo, restlessness, dry mouth, cardio-toxic.

DRUG-HERB INTERACTION-

This is one of the most common issues with the ADR of a specific medicine. There is a misconception that natural drugs are safe and free of toxins. However,

according to Ayurveda, every material in the Universe is medicine, so it has some medicinal effect when used appropriately. Activity could be synergistic, decreased antagonistic, or increased bioavailability.^[6]

A few examples are bleeding after taking Phenprocoumon with ginger, warfarin with Fenugreek, claw, garlic, mango, or papaya.^[7,8]

Lithium activity decreases when consumed with herbal diuretics such as Tribulus terrestris and Syzygium cumini.^[9]

OVERDOSE-

According to the current FDA definition of ADR^[10], overdose is the primary cause of ADR. A patient taking *Tribhuvan kirti rasa* along with *Sanjivani vati* developed severe prostration, vomiting and headache due to overdose of *vatsnabh*.^[11]

GMP GUIDELINES IN AYURVEDA-

The process starts with standardising raw materials [12] and progresses through quality checks, storage^[13] and preparation. The finished product must meet pharmaceutical standards.^[14] When preparing mineral and poisonous medications, it is essential to purify raw materials and use appropriate processing techniques^[15]. Quality concerns are handled under AFI (Ayurvedic Formulary of India), developed by the Department of AYUSH (Ayurveda, Unani, Siddha) and CCRAS (Central Council for Research in Ayurveda and Siddha).

ROLE OF AYUSH SURKSHA^[16]-

"AYUSH Suraksha" refers to the safety framework designed by the Ministry of AYUSH, Government of India, to ensure the safe use of ancient Indian medical systems such as *Ayurveda*, Yoga, Unani, Siddha, and Homoeopathy.

This includes:

1. Pharmacovigilance programs for monitoring and reporting adverse drug reactions (ADRs) from AYUSH medicines.
2. Regulatory procedures to ensure the quality, safety, and efficacy of AYUSH medicines
3. Initiatives to raise awareness and train practitioners, researchers, and the general public

4. Standardisation of formulations, correct labelling of constituents, and dose.

BENEFITS OF AYUSH SURKSHA –

AYUSH Suraksha promotes the safety of traditional medicines by monitoring adverse drug reactions, improving the quality and standardisation of *Ayurvedic* formulations, and building public trust through scientific validation and awareness campaigns.

CONCLUSION

Ayurveda, based on natural principles and ancient medicinal practices, is not immune to safety concerns, particularly in the modern context of widespread use and self-medication. This article has shown that adverse drug reactions (ADRs) linked with Ayurvedic medications can be caused by a variety of factors, including heavy metal contamination, incorrect toxic component purification, insufficient standardisation, herb-drug interactions, and overdosage. Predictable reactions from metallic preparations and poisonous plants highlight the significance of strict quality control and appropriate therapeutic use. The growing recognition of these challenges has led to significant initiatives, such as the Ayush Suraksha program, which aims to improve pharmacovigilance, regulatory surveillance, and public and practitioner awareness. Implementing Good Manufacturing Practices (GMP), promoting evidence-based teaching, and enforcing standard treatment guidelines are crucial for ensuring that Ayurvedic medications are used safely and adequately. Only through such efforts will Ayurveda reach its full potential as a safe, effective, and widely accepted medical system.

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