EDUZONE: International Peer Reviewed/Refereed Multidisciplinary Journal (EIPRMJ), ISSN: 2319-5045
Volume 15, Issue 2, July-December, 2026, Available online at: www.eduzonejournal.com

Comparative Toxicological Evaluation of Selected Ayurvedic Formulations: Heavy-Metal Content, Oxidative Stress and Organ-Specific Toxicity: A Review

Dr. Bhavana. S. Tokapure

Assistant Professor, Agadtantra Department, Sau. Vandana N. Tasgaonkar Ayurved Mahavidyalaya

ABSTRACT

Ayurveda is a traditional Indian system of medicine widely used for health promotion and disease management. Ayurvedic medicines include herbal preparations as well as herbo-mineral and mineral formulations. Although these medicines have a long history of use, the presence of toxic metals such as lead (Pb), mercury (Hg), arsenic (As), and cadmium (Cd) in some products has raised important safety concerns. Metals may be intentionally incorporated into certain *Rasa Shastra* preparations or may enter medicines unintentionally through contaminated raw materials, soil, water, processing, packaging, or inadequate quality control. Published analytical studies have demonstrated considerable variation in metal concentrations among Ayurvedic products. [1–4]

Heavy metals are capable of inducing toxicity through multiple mechanisms, among which oxidative stress is particularly important. Metal exposure may increase reactive oxygen species, deplete glutathione, impair antioxidant enzymes, disturb mitochondrial function, promote lipid peroxidation, and damage proteins and DNA. These changes can ultimately produce inflammation, apoptosis, and organ dysfunction. [5–7] The liver and kidneys are important target organs because of their roles in metabolism and excretion, while the nervous system is highly vulnerable to lead and mercury. Hematological, cardiovascular, and reproductive effects have also been described.(6)

The presence of a heavy metal in a formulation does not by itself establish clinical toxicity; actual risk depends on chemical form, concentration, dose, bioavailability, duration of exposure, and individual susceptibility. Therefore, Ayurvedic medicines should be evaluated through a comprehensive quality and safety framework. This review summarizes evidence concerning heavy-metal occurrence, oxidative-stress mechanisms, organ-specific toxicity, and quality-control requirements for Ayurvedic formulations.

Keywords: Ayurveda; Ayurvedic medicines; heavy metals; lead; mercury; arsenic; cadmium; oxidative stress; hepatotoxicity; nephrotoxicity; neurotoxicity; quality control.

INTRODUCTION

Ayurveda is one of the major traditional systems of medicine originating in India and remains an important component of healthcare in India and other countries. Ayurvedic therapeutics include dietary and lifestyle interventions together with medicinal preparations derived mainly from plants but also from minerals, metals, and animal materials. [1,11] The formulation category is therefore highly diverse, ranging from simple herbal powders and decoctions to complex herbo-mineral preparations.

The toxicological evaluation of Ayurvedic medicines has gained increasing importance with their expanding use and international availability. The major safety concern in relation to some formulations is exposure to toxic metals, particularly lead, mercury, arsenic, and cadmium. These elements can produce cumulative toxicity when exposure is sufficiently high or prolonged. [2–6]

A distinction should be made between intentional and unintentional metal presence. In some *Rasa Shastra* formulations, metals and minerals are deliberately incorporated as pharmaceutical ingredients and subjected to traditional processing. In purely herbal medicines, heavy metals are generally contaminants arising from environmental pollution, agricultural soil, irrigation water, manufacturing, equipment, or storage. [1,4,12]

The scientific literature has documented the occurrence of toxic metals in marketed Ayurvedic products. Saper et al. reported that approximately one-fifth of Ayurvedic medicines purchased through the internet contained detectable lead, mercury, or arsenic. [3] Earlier work examining Ayurvedic herbal medicine products sold in the Boston area also found substantial metal contamination and concluded that some products could result in excessive daily metal exposure. [2] A subsequent Indian study of Ayurvedic formulations similarly demonstrated considerable variation in metal concentrations. [4]

These findings do not justify considering all Ayurvedic medicines unsafe. Rather, they indicate the need for formulation-specific quality assessment. Ayurvedic preparations differ greatly in composition, processing, dose, and intended duration of use. Consequently, safety should be assessed on the basis of actual exposure rather than the simple presence or absence of a metal.

Heavy Metals in Ayurvedic Formulations

Lead is a non-essential toxic metal and one of the best-established environmental toxicants. It has no physiological requirement and may affect the nervous, hematopoietic, renal, cardiovascular, and reproductive systems. [6,8]

Lead may occur in Ayurvedic medicines through intentional incorporation in some mineral preparations or through contamination of herbal raw materials. Soil and water contamination are particularly relevant because medicinal plants can absorb metals from their growing environment. Poor manufacturing practices may provide additional sources of contamination. [2,12]

Lead toxicity involves several mechanisms. It can interfere with calcium-dependent processes, inhibit enzymes involved in heme synthesis, alter neurotransmission, impair mitochondrial function, and increase oxidative stress. The developing nervous system is especially sensitive, making children and pregnant women important vulnerable populations. Chronic exposure may result in cognitive and behavioral effects, anemia, hypertension, renal injury, and peripheral neurological abnormalities. [6,8]

Mercury is particularly relevant in Ayurvedic toxicology because mercury-containing substances have traditionally been incorporated into some *Rasa Shastra* formulations. Mercury occurs in different chemical forms, and toxicity depends strongly on speciation, absorption, and tissue distribution. [1,7]

Mercury has a strong affinity for sulfhydryl groups and can interfere with proteins and enzymes. It can reduce intracellular glutathione, disturb antioxidant defenses, alter mitochondrial function, and increase oxidative injury. The kidneys and nervous system are important target organs. Neurological manifestations may include tremor, sensory abnormalities, cognitive disturbance, and motor dysfunction, whereas renal exposure may produce tubular injury and proteinuria. [5,7]

Arsenic is a toxic metalloid with several chemical forms. Inorganic arsenic is particularly important because chronic exposure is associated with dermatological, vascular, neurological, hepatic, and carcinogenic effects. [9]

Arsenic may enter Ayurvedic preparations through intentional use of arsenic-containing mineral substances or through environmental contamination. Its toxicity involves oxidative stress, mitochondrial dysfunction, interference with sulfhydryl groups, altered cellular signaling, DNA damage, and epigenetic effects. [5,9]

Cadmium is a non-essential environmental toxicant. In Ayurvedic products it is generally considered an unintended contaminant rather than a therapeutic ingredient. Medicinal plants may acquire cadmium from polluted soil, fertilizers, industrial emissions, or contaminated water. [10,12]

The kidney is a major target of chronic cadmium exposure. Accumulation within renal tissue may cause tubular dysfunction, while long-term exposure can contribute to skeletal and systemic toxicity. Cadmium also promotes oxidative stress and disrupts cellular antioxidant defenses. [5,10]

Sources of Heavy-Metal Contamination

Heavy-metal occurrence in Ayurvedic medicines can result from several stages of the production chain.

Environmental contamination

Medicinal plants may absorb metals from contaminated soil and irrigation water. Industrial activity, mining, wastewater irrigation, atmospheric deposition, and inappropriate waste disposal may increase environmental metal levels. WHO

quality-control guidance therefore recognizes testing for arsenic and toxic metals as an important component of medicinal-plant quality assessment. [12,13]

Raw-material quality
Incorrect botanical identification, adulteration, substitution, or use of poor-quality raw materials may increase the likelihood of contamination. Collection from polluted geographical areas may further increase metal content.

Manufacturing
Manufacturing quality is particularly important for mineral and herbo-mineral medicines. Traditional processing methods require appropriate control of raw materials and processing conditions. Deviations from standardized procedures may result in inconsistent final products. Quality systems should therefore include validated processes, documentation, and batch testing.

Packaging and storage

Although contamination from packaging is less frequently reported than contamination from raw materials, inappropriate storage and contact with unsuitable materials can potentially affect product quality. Overall safety must therefore be considered throughout the entire manufacturing and distribution chain.

Oxidative Stress as a Mechanism of Heavy-Metal Toxicity

Oxidative stress is one of the major mechanisms linking heavy-metal exposure to cellular and organ injury. Under normal physiological conditions, reactive oxygen species are continuously generated and controlled by antioxidant defenses. Toxic metal exposure can disturb this balance by increasing ROS generation and decreasing antioxidant capacity. [5,6]

Heavy metals may interfere with mitochondrial electron transport, stimulate inflammatory pathways, inhibit antioxidant enzymes, and decrease glutathione availability. This results in accumulation of reactive species such as superoxide and hydrogen peroxide and, under appropriate conditions, more reactive secondary species. [5]

Glutathione depletion- Glutathione is an important intracellular antioxidant. Mercury and other toxic metals can interact with thiol-containing molecules and reduce cellular antioxidant capacity. Depletion of glutathione increases susceptibility to oxidative damage. [5,7]

Lipid peroxidation- Reactive oxygen species attack membrane polyunsaturated fatty acids and initiate lipid peroxidation. This can disrupt cell membranes, alter membrane permeability, and generate reactive aldehydes that further damage cellular proteins.

Protein and enzyme damage- Oxidation of proteins may alter enzyme activity, membrane transport, signaling, and structural integrity. Metals can additionally bind directly to proteins and modify their normal function.

DNA damage- Oxidative stress can produce DNA base modification and strand damage. Arsenic may additionally interfere with DNA repair and epigenetic regulation, providing a mechanistic link between chronic exposure and carcinogenesis. [9]
Mitochondrial dysfunction and apoptosis-Mitochondria are important sources and targets of ROS. Heavy metals may impair mitochondrial membrane potential, ATP generation, and electron transport, creating a cycle of increasing oxidative stress. Severe cellular injury may ultimately activate apoptotic pathways.

Thus, oxidative stress is not an isolated event but a connecting mechanism through which heavy metals can produce inflammation, cellular dysfunction, and organ-specific toxicity. [5,6]

Liver toxicity

The liver is a major organ of metabolism and detoxification and is therefore an important target for toxic substances. Heavy metals may induce hepatic oxidative stress, mitochondrial dysfunction, inflammatory signaling, and cellular injury. Lead, mercury, arsenic, and cadmium have all been associated with hepatic oxidative damage in toxicological literature. [5,9,10]
Potential manifestations include increased liver enzymes, hepatocellular injury, inflammation, and, with prolonged exposure, structural changes. However, liver injury in a patient consuming an Ayurvedic formulation cannot automatically be attributed to heavy metals. Botanical ingredients, adulterants, drug interactions, alcohol, infection, and metabolic disease must also be considered.

Kidney toxicity
The kidney is particularly vulnerable because it plays a major role in filtration and excretion. Lead, mercury, and cadmium can accumulate within renal tissues and produce tubular injury. [6,7,10]

Oxidative stress, mitochondrial dysfunction, altered transport processes, and inflammation contribute to renal toxicity. Clinical manifestations may include proteinuria, altered renal function, and tubular dysfunction. Chronic low-level exposure is important because renal injury may progress gradually without prominent early symptoms.

Neurotoxicity
Lead and mercury have well-established neurotoxic properties. Lead can interfere with neuronal signaling, calcium-dependent processes, synaptic function, and brain development. [6,8] Mercury can alter neuronal proteins, mitochondrial function, and redox balance. [7]

Possible manifestations include cognitive impairment, behavioral changes, memory disturbance, sensory abnormalities, tremor, and peripheral neuropathy. Developing children are particularly vulnerable to lead exposure because neurological development is highly sensitive to toxic insults.

Hematological toxicity
Lead interferes with enzymes involved in heme synthesis and may therefore produce anemia. This mechanism is particularly relevant when patients present with otherwise unexplained anemia and have a history of consuming products that may contain lead. [8]

Cardiovascular toxicity
Chronic exposure to lead and arsenic has been associated with vascular dysfunction and increased cardiovascular risk. Oxidative stress can impair endothelial function, reduce nitric oxide availability, and promote inflammation. [6,9]

Reproductive and developmental toxicity
Lead, cadmium, arsenic, and mercury may affect reproductive processes and fetal development. The developing fetus and young children may be particularly sensitive to toxic-metal exposure. Therefore, long-term use of inadequately characterized metal-containing products requires special caution during pregnancy and childhood. [6,9,10]

Comparative Toxicological Consideration of Ayurvedic Formulations

Feature	Herbal formulations	Herbo-mineral formulations
Intentional toxic-metal content	Usually absent	May be present
Environmental contamination	Possible	Possible
Main safety concerns	Contamination, adulteration, intrinsic herb toxicity	Metal exposure plus other formulation risks
Heavy-metal testing	Important	Particularly important
Need for batch standardization	High	Very high
Long-term exposure concern	Depends on product	Depends strongly on metal, dose and formulation

It is scientifically inappropriate to describe all herbal formulations as completely safe or all herbo-mineral formulations as toxic. Herbal medicines may contain environmental contaminants and may cause adverse effects unrelated to metals, while properly manufactured mineral preparations require specific evidence concerning their composition, processing, dose, and bioavailability. [1,4,14] Therefore, the correct approach is risk-based evaluation of each formulation.

Quality Control and Regulatory Considerations
Quality control is the most important practical strategy for minimizing heavy-metal-related risk. WHO guidance recommends assessment of contaminants, including arsenic and toxic heavy metals, in medicinal plant materials. [12,13]
In India, the Pharmacopoeia Commission for Indian Medicine and Homoeopathy provides official pharmacopoeial standards for Indian medicines. The Commission states that pharmacopoeial standards include limits for heavy/toxic metals, pesticide residues, aflatoxins, and microbial contamination. [15]

Modern analytical techniques such as atomic absorption spectroscopy and inductively coupled plasma–mass spectrometry can be used for sensitive multi-element detection. However, analytical measurement should ideally be interpreted together with intended dose, exposure duration, and, where necessary, chemical speciation. [4,15]

Good Manufacturing Practice is also essential. Appropriate raw-material procurement, authentication, controlled processing, sanitation, equipment maintenance, documentation, and finished-product testing reduce the risk of contamination and batch variability.

Pharmacovigilance complements laboratory quality control. Patients may present with non-specific symptoms that are difficult to attribute to a traditional medicine unless the clinician specifically asks about its use. In India, the Ayush Suraksha pharmacovigilance system supports monitoring of adverse events associated with AYUSH medicines. [16]

The WHO Global Traditional Medicine Strategy 2025–2034 also emphasizes evidence, safety, quality assurance, regulation, and appropriate integration of traditional medicines into health systems. [17]

DISCUSSION

Available evidence demonstrates that heavy metals can occur in some Ayurvedic medicines and that excessive exposure can produce significant toxicity. The 2004 Saper study and the 2008 internet-based survey remain important evidence demonstrating the need for heavy-metal monitoring of marketed products. [2,3] More recent Indian data continue to demonstrate variable concentrations of mercury, arsenic, lead, cadmium, and other metals in Ayurvedic formulations.

However, these findings should not be generalized to every Ayurvedic product. There is substantial heterogeneity in formulation composition. A simple herbal *Churna* and a herbo-mineral *Rasaushadhi* have very different toxicological profiles. Similarly, a product produced under validated quality standards cannot automatically be considered equivalent to an unregulated product purchased from an unknown source.

Another important issue is that heavy-metal concentration alone does not establish toxicity. A scientifically meaningful evaluation requires consideration of the chemical form, total amount ingested, daily exposure, duration of treatment, gastrointestinal absorption, tissue distribution, and individual susceptibility. Therefore, comparative toxicological evaluation should integrate analytical data with toxicological principles.

Oxidative stress provides a common mechanistic pathway connecting heavy-metal exposure with liver, kidney, brain, cardiovascular, and reproductive injury. Increased ROS generation, glutathione depletion, mitochondrial dysfunction, lipid peroxidation, protein oxidation, DNA injury, and inflammation can occur together rather than independently. [5,6]

The major public-health priority is therefore not simply to identify whether metals exist in Ayurvedic medicines, but to ensure that products placed on the market have a scientifically acceptable safety profile. This requires systematic raw-material control, validated manufacturing, appropriate analytical testing, pharmacopoeial compliance, and active pharmacovigilance.

CONCLUSION

Heavy-metal exposure is a formulation-specific safety concern in Ayurveda, with lead, mercury, arsenic, and cadmium entering products through intentional use, contamination, or poor manufacturing. Excessive exposure can trigger oxidative stress, mitochondrial dysfunction, inflammation, DNA damage, and organ toxicity, especially in the liver, kidneys, and nervous system, while also affecting hematological, cardiovascular, reproductive, and developmental health. Importantly, not all Ayurvedic medicines are inherently toxic—the risk depends on formulation, metal species, dose, bioavailability, duration, manufacturing quality, and patient susceptibility. Ensuring safety requires authentic raw materials, standardized manufacturing, heavy-metal testing, pharmacopoeial compliance, appropriate clinical use, and pharmacovigilance. Future research should emphasize exposure-based risk assessment and long-term clinical evaluation to preserve Ayurveda's therapeutic potential while enhancing scientific credibility and patient safety.

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