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Review Article

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"HEAVY METALS IN AYURVEDIC FORMULATIONS: RISK AND PHARMACOLOGICAL SAFETY STUDIES"

Dr. Jalpa Gandhi[1]

AFFLIATIONS:
1. CEO, Ira Consultancy & Research Organisation, Bhosari, Pune, Maharashtra 411026

CORRESPONDENCE:
Dr. Jalpa Gandhi
EMAILID: ceo@icro.co.in

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ABSTRACT

Introduction: Ayurvedic formulations often contain metals and minerals intentionally processed through *Shodhana* and *Marana* to produce *Bhasma* (calcined preparations). While these herbo-mineral formulations have been used therapeutically for centuries, concerns have emerged regarding heavy metal toxicity, especially when preparations are improperly manufactured. Modern toxicological studies highlight risks of lead, mercury, and arsenic contamination, whereas standardized formulations have demonstrated safety in clinical use. This review examines the traditional rationale, risks, and pharmacological safety studies of heavy metals in Ayurveda. **Methods:** A systematic review was conducted by analyzing Ayurvedic classical texts (*Rasatarangini, Rasaratna Samuccaya, Charaka Samhita, Sushruta Samhita*), pharmacopoeial standards, and modern studies retrieved from PubMed, Scopus, Web of Science, and AYUSH Research Portal. Inclusion criteria were experimental toxicology, pharmacological safety studies, and clinical evaluations of heavy-metal-containing Ayurvedic formulations. Exclusion criteria included non-peer-reviewed reports and non-Ayurvedic detoxification methods. **Results:** Classical texts emphasize purification (*Shodhana*) and incineration (*Marana*) to detoxify metals and convert them into therapeutic nanoparticles. Modern analytical studies confirm that properly prepared *Bhasma* exist as nano- to micro-particles with organometallic complexes, distinct from raw toxic metals. However, non-standard preparations and contamination contribute to reported cases of lead nephropathy, arsenic neuropathy, and mercury toxicity. Preclinical studies show that standardized *Bhasmas* (e.g., *Abhraka Bhasma, Swarna Bhasma, Tamra Bhasma*) are safe within therapeutic ranges, with some demonstrating immunomodulatory, antioxidant, and adaptogenic activity. Clinical evidence supports safety when pharmacopoeial standards are met. **Discussion:** Traditional Ayurvedic processing aligns with principles of detoxification and biotransformation. Modern studies confirm safety for standardized formulations but raise concerns regarding unregulated manufacturing. Future directions include stringent quality control, advanced analytical validation, and large-scale clinical safety trials. **Conclusion:** Heavy metals in Ayurvedic formulations pose risks when improperly processed but can be safe and therapeutically beneficial when classical *Rasa Shastra* methods and pharmacopoeial standards are followed. Integrating Ayurveda with modern toxicological validation is essential for ensuring safety in global healthcare.

KEYWORDS: Ayurveda, *Bhasma*, heavy metals, pharmacological safety, toxicity

INTRODUCTION

Ayurveda, one of the world's oldest medical systems, incorporates both herbal and mineral formulations in therapeutics. *Rasa Shastra*—the branch dealing with metals and minerals—describes the preparation of *Bhasmas* (calcined metallic and mineral ashes) through elaborate purification (*Shodhana*) and incineration (*Marana*) processes.[1-3] Formulations containing mercury (*Parada*), lead (*Naga*), arsenic (*Haritala*), copper (*Tamra*), gold (*Swarna*), and iron (*Lauha*) are traditionally employed for a wide range of disorders including anemia, arthritis, neurological diseases, and metabolic syndromes. [4-5]

Concerns over heavy metal toxicity in Ayurveda have gained prominence due to sporadic reports of lead poisoning, mercury accumulation, and arsenic-related toxicities, particularly in unregulated formulations. [6-7] Media reports and case studies have raised global apprehension about the safety of Ayurvedic preparations, leading to debates about their therapeutic validity. However, it is critical to distinguish between contaminated, improperly manufactured formulations and standardized pharmacopoeial *Bhasmas* prepared through traditional methods.[8]

The aim of this review is to analyze heavy metals in Ayurvedic formulations from two perspectives: (1) the traditional rationale, methods of purification, and therapeutic justifications; and (2) modern toxicological and pharmacological safety evaluations. The objectives are to summarize classical references, critically examine risks associated with heavy metals, and evaluate experimental and clinical evidence validating their safety when processed correctly.[9-10]

MATERIALS AND METHODS

A systematic literature review was carried out between April and August 2025. Sources included:

1. **Classical Ayurvedic texts**: *Charaka Samhita, Sushruta Samhita, Rasatarangini, Rasaratna Samuccaya, Bhaishajya Ratnavali,* and *Bhavaprakasha Nighantu*.[11]
2. **Databases searched**: PubMed, Scopus, Web of Science, AYUSH Research Portal, and Google Scholar.[12]
3. **Search terms**: "Ayurveda heavy metals," "*Bhasma* safety," "*Rasa Shastra* toxicology," "lead poisoning Ayurveda," "pharmacological safety Ayurvedic formulations."[13]
4. **Inclusion criteria**:[14]
   - Experimental toxicology studies of *Bhasmas*.
   - Analytical studies on heavy metal content.
   - Pharmacological studies of heavy-metal formulations.
   - Clinical trials or safety reports.
5. **Exclusion criteria**:[15]
   - Non-Ayurvedic detoxification studies.
   - Case reports without laboratory validation.
   - Non-peer-reviewed anecdotal claims.

Type of studies reviewed: Pharmacognostic, analytical (XRD, SEM, ICP-MS), preclinical toxicological (animal models), clinical evaluations, and regulatory pharmacopoeial standards were included.

OBSERVATION AND RESULTS

1. Classical Perspectives on Heavy Metals in Ayurveda

Ayurvedic classics recognize metals as potentially toxic in raw form. *Rasa Shastra* prescribes *Shodhana* (purification) using herbal juices, cow's milk, urine, ghee, and decoctions to remove impurities, followed by *Marana* (calcination) to convert metals into bio-assimilable *Bhasma*. *Charaka Samhita* (Chikitsa Sthana 1) and *Sushruta Samhita* emphasize that improperly processed metals act as poisons.

For example:

- *Swarna Bhasma* (gold ash) is considered a *Rasayana* for longevity and immunity.
- *Tamra Bhasma* (copper ash) is used in liver disorders and metabolic dysfunction.
- *Naga Bhasma* (lead ash) and *Vanga Bhasma* (tin ash) are indicated in reproductive and urinary disorders.
- *Abhraka Bhasma* (mica ash) is used in respiratory and chronic debilitating diseases.

Thus, Ayurveda recognized toxicity risks and provided methods to render heavy metals therapeutically safe.

2. Analytical Characterization of *Bhasmas*

Modern studies using XRD, SEM, TEM, and ICP-MS reveal that *Bhasmas* are not metallic elements in raw form but exist as metal oxides, sulfides, or silicates in nano- to micro-crystalline states.

- *Swarna Bhasma*: Particle size ranges between 30–60 nm, showing organometallic complexes with proteins and lipids.

- *Abhraka Bhasma*: Contains silica, alumina, and trace elements, existing as crystalline nanoparticles.
- *Tamra Bhasma*: Predominantly copper oxide nanoparticles.
- *Naga Bhasma*: Shows lead sulfide as the primary compound, different from elemental lead.

These transformations explain reduced toxicity compared to raw metals.

3. Toxicological Risks from Improper Preparations

Case studies have reported heavy metal poisoning linked to Ayurvedic formulations, especially when products are prepared without classical *Shodhana* or contaminated during manufacturing.

- **Lead toxicity**: Chronic nephropathy and cognitive impairment have been reported in patients consuming adulterated *Naga Bhasma*.
- **Mercury toxicity**: Cases of tremors and renal dysfunction linked to improperly prepared mercurial formulations (*Rasa Sindura*).
- **Arsenic exposure**: Peripheral neuropathy and skin pigmentation linked to contaminated formulations.

Such incidents highlight the necessity of adhering to pharmacopoeial standards.

4. Preclinical Safety Studies

a. *Swarna Bhasma:* Studies in rats demonstrate no acute or subchronic toxicity at therapeutic doses. It exhibits immunomodulatory and antioxidant properties.

b. *Abhraka Bhasma:* Safe in long-term administration; shown to enhance hemoglobin levels and antioxidant defense in animal models.

c. *Tamra Bhasma:* Exhibits dose-dependent safety; toxicity reported only at supratherapeutic levels.

d. *Rasa Sindura* (mercurial compound): Studies show mercury exists as cinnabar (HgS), poorly absorbed in the gut, explaining reduced toxicity.

e. *Naga Bhasma:* Animal studies indicate safe hematological and hepatic parameters when administered within prescribed doses.

5. Clinical Evidence on Safety

- *Swarna Bhasma* has been tested in controlled clinical trials for rheumatoid arthritis and found safe with no evidence of nephrotoxicity or hepatotoxicity.
- *Abhraka Bhasma* used in chronic respiratory conditions demonstrated improved pulmonary function without adverse biochemical markers.
- *Rasa Sindura* used in herbo-mineral formulations has been reported safe in multiple studies, provided pharmacopoeial methods were followed.

6. Regulatory and Pharmacopoeial Standards

The *Ayurvedic Pharmacopoeia of India* specifies acceptable limits of heavy metals, particle size, and preparation methods. WHO guidelines for herbal medicines also emphasize good manufacturing practice (GMP), batch-to-batch quality control, and heavy metal quantification.

7. Synthesis of Findings

- **Ayurvedic view:** Metals can be therapeutic if processed via *Shodhana* and *Marana*.
- **Modern validation:** Standardized *Bhasmas* are structurally distinct from raw metals, showing favorable safety profiles.
- **Risk:** Adulterated, contaminated, or unstandardized formulations pose real health threats.
- **Solution:** Stringent adherence to pharmacopoeial standards, advanced analytical methods, and regulatory monitoring.

DISCUSSION

The debate on heavy metals in Ayurveda arises primarily from two perspectives: the classical Ayurvedic standpoint that emphasizes safety through *Shodhana* and *Marana*, and modern concerns about toxicity from lead, mercury, and arsenic exposure. These seemingly opposing views can be reconciled by understanding that properly prepared *Bhasmas* are chemically distinct from their raw metallic forms.[16]

Modern analytical evidence demonstrates that *Bhasmas* largely exist as oxides, sulfides, or silicates in nano- or micro-particulate form. These modifications alter bioavailability, toxicity, and pharmacokinetics. For instance, mercury in *Rasa Sindura* is present as cinnabar (HgS), which is poorly absorbed and less toxic compared to organic mercury compounds. Similarly, lead in *Naga Bhasma* exists as PbS, chemically different from elemental lead or lead acetate, known for

nephrotoxicity.[17]

Animal and clinical studies reinforce this distinction. Standardized preparations have shown safety within therapeutic ranges, with some demonstrating pharmacological benefits such as immunomodulation, antioxidant activity, and tissue regeneration. Conversely, case reports of heavy metal poisoning are predominantly linked to non-standardized products, poor manufacturing practices, or spurious formulations sold in unregulated markets.[18]

This dichotomy underscores the importance of quality control. The Ayurvedic Pharmacopoeia of India and WHO have set clear guidelines for permissible heavy metal content, manufacturing practices, and analytical testing. Yet, lapses in regulatory enforcement and lack of patient awareness continue to cause health risks.[19]

Gaps remain in our understanding. Most preclinical studies are limited in scope, and large-scale, randomized, placebo-controlled clinical trials are sparse. Mechanistic insights into how *Bhasmas* interact at the molecular and cellular level are underexplored. Advanced methods such as proteomics, metabolomics, and molecular imaging can provide clarity. Furthermore, international mistrust persists, partly due to inadequate dissemination of scientific evidence supporting the safety of standardized formulations.[20]

Future prospects lie in interdisciplinary collaboration. Ayurvedic scholars and modern scientists must co-develop standardized preparation protocols, validated analytical markers, and robust toxicological evaluations. Public education campaigns on the importance of purchasing formulations from certified sources will reduce risks of toxicity. Integrating ancient wisdom with modern science can transform *Rasa Shastra* from a subject of controversy into a model of innovative pharmaceutics.[20]

CONCLUSION

This review highlights the dual perspective of heavy metals in Ayurvedic formulations: risk when improperly manufactured, and therapeutic safety when prepared according to classical *Rasa Shastra* protocols and pharmacopoeial standards. Classical texts clearly emphasized that metals in raw form are toxic and only safe after *Shodhana* and *Marana*. Modern analytical evidence corroborates this by demonstrating that *Bhasmas* are structurally different from raw metals, existing as organometallic nanoparticles with reduced bioavailability of toxic species.

Preclinical and clinical studies support the safety of standardized *Bhasmas*, with many demonstrating beneficial pharmacological properties. Conversely, toxicity reports largely stem from non-standardized, contaminated, or counterfeit preparations.

Therefore, the risks associated with heavy metals in Ayurveda are not inherent to the tradition but to lapses in manufacturing quality and regulatory oversight. The practical implication is that strict adherence to pharmacopoeial standards, quality assurance, and modern analytical validation are essential. Interdisciplinary research bridging Ayurveda and toxicology will enhance global confidence in the safe use of Ayurvedic formulations.

In conclusion, heavy metals in Ayurveda, when processed correctly, exemplify the sophistication of traditional pharmaceutics and offer opportunities for safe, effective, and innovative therapeutic applications in contemporary medicine.

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