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"HEAVY METAL CONCERNS IN AYURVEDIC FORMULATIONS: MYTHS AND SCIENTIFIC CLARIFICATIONS"

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ABSTRACT

Introduction: Ayurvedic formulations, particularly those containing *Rasa Aushadhis* and herbo-mineral preparations, have been criticized for potential heavy metal toxicity. However, these concerns are often generalized and not always based on rigorous scientific evaluations. **Methods:** A comprehensive literature search was conducted across PubMed, Scopus, Web of Science, and AYUSH Research Portal (2000–2025). Classical Ayurvedic texts (*Charaka Samhita*, *Sushruta Samhita*, *Rasa Ratna Samucchaya*) were also reviewed to understand traditional perspectives. Both experimental studies and clinical reports on heavy metal content, bioavailability, safety assessments, and detoxification (Shodhana) methods were included. **Results:** Evidence reveals that heavy metals like mercury, lead, and arsenic are intentionally used in Ayurveda only after extensive purification and processing, which transforms them into bioavailable yet non-toxic forms. Classical methods such as *Shodhana* and *Marana* reduce toxicity and alter physicochemical properties. Modern analytical studies confirm differences between raw metals and finished Ayurvedic formulations, with many preparations showing safe levels within WHO permissible limits. Nevertheless, instances of toxicity are often linked to poor-quality manufacturing, lack of adherence to traditional procedures, or unregulated commercial products. **Discussion:** The myths regarding heavy metal toxicity in Ayurveda largely stem from extrapolating data on raw heavy metals, without considering their processed forms. While genuine concerns exist regarding standardization and regulatory monitoring, scientific clarifications demonstrate that traditionally prepared formulations are generally safe. **Conclusion:** Heavy metal toxicity in Ayurveda is not an inherent flaw but a quality-control issue. Strengthening Good Manufacturing Practices (GMP), ensuring standardization, and conducting more rigorous clinical safety studies can bridge the gap between tradition and modern science.

KEYWORDS: Ayurveda, heavy metals, herbo-mineral formulations, safety, toxicity

INTRODUCTION

Ayurveda, the ancient system of medicine practiced in India for millennia, employs a holistic approach to health and disease management. Among its unique contributions are herbo-mineral formulations (*Rasaushadhis*), which have been valued for their potency, rapid action, and efficacy in chronic and complex diseases[1-2]. These formulations often incorporate metals and minerals, carefully processed through detoxification (*Shodhana*) and incineration (*Marana*) procedures to ensure safety and therapeutic potential[3-4].

Despite this long tradition, modern criticisms have questioned the safety of such formulations, particularly due to concerns regarding heavy metal content. Reports of lead, mercury, and arsenic toxicity in some Ayurvedic products have raised alarm internationally[5-6]. However, a significant portion of this skepticism arises from limited understanding of Ayurvedic pharmaceutics, improper manufacturing practices, or studies focusing on raw metals rather than traditionally processed preparations[7-8].

The present review aims to critically examine the myths and realities of heavy metal concerns in Ayurvedic formulations. The objectives are: (i) to review traditional Ayurvedic concepts regarding metals and their detoxification; (ii) to evaluate scientific evidence on safety and toxicity of Ayurvedic formulations; (iii) to analyze causes behind reported cases of toxicity; and (iv) to provide evidence-based clarifications for bridging the gap between traditional wisdom and modern toxicology[9-10].

MATERIALS AND METHODS

A systematic literature review was undertaken following PRISMA guidelines.

Databases searched: PubMed, Scopus, Web of Science, AYUSH Research Portal, Google Scholar.

Search strategy: Keywords included "Ayurveda heavy metals," "Rasaushadhi safety," "Bhasma toxicity," "Ayurvedic herbo-mineral formulations," "Shodhana detoxification." Boolean operators (AND, OR) were used for refining searches[11].

Inclusion criteria: [12]

Studies (2000–2025) reporting chemical analysis, toxicological assessment, pharmacological evaluation, or clinical trials on Ayurvedic formulations containing metals/minerals. Articles discussing *Shodhana*, *Marana*, or other detoxification processes. Reviews, meta-analyses, experimental studies, and clinical case reports.

Exclusion criteria: [13]

- Non-scientific blogs, anecdotal claims without evidence.
- Studies reporting unregulated/unverified Ayurvedic-like preparations without GMP adherence.
- Duplicate publications.

Classical sources: *Charaka Samhita, Sushruta Samhita, Rasa Ratna Samucchaya, Ayurveda Sara Sangraha*, and authoritative commentaries[14].

Data extraction and synthesis: Selected studies were thematically analyzed under categories: (i) traditional Ayurvedic principles, (ii) analytical studies, (iii) toxicological studies, (iv) clinical safety reports, and (v) regulatory perspectives[15].

OBSERVATION AND RESULTS

1. Traditional Ayurvedic Perspectives on Metals

Ayurveda classifies metals (*dhatus*) and minerals (*uparasa, ratna, loha*) as powerful therapeutic agents when properly processed. Texts like *Rasa Ratna Samucchaya* detail purification (*Shodhana*) techniques such as boiling, triturating with herbal juices, and heating cycles, which are believed to detoxify raw metals. *Marana* (calcination) converts metals into fine powders (*Bhasma*) with altered physicochemical properties, rendering them assimilable at the cellular level. Classical texts emphasize that unprocessed metals are highly toxic and should never be consumed.

Gold (*Swarna*), silver (*Rajata*), mercury (*Parada*), lead (*Naga*), and arsenic (*Haritala, Manashila*) are described as therapeutic only after undergoing elaborate purification. These preparations are claimed to enhance immunity, longevity, and therapeutic efficacy in chronic disorders. The concept aligns with modern pharmacology, where toxicity is dose- and form-dependent.

2. Analytical Studies on Ayurvedic Formulations

Modern spectroscopic techniques (AAS, ICP-MS, SEM, XRD) have analyzed Ayurvedic *Bhasmas*. Results indicate that finished products differ markedly from raw metals:

- **Mercury in Rasasindura:** Found predominantly in cinnabar form (HgS), which is poorly soluble and has minimal bioavailability compared to elemental mercury.

- **Lead in Naga Bhasma:** Exists as lead sulfide (PbS), far less toxic than soluble lead salts.
- **Arsenic in Hartala Bhasma:** Present mainly as arsenic trisulfide (As2S3), again with low bioavailability.

Particle size analyses show that Bhasmas contain nano- to micro-scale particles embedded in organic matrices, enhancing bioavailability and safety. Multiple studies confirm that properly prepared formulations often have metal concentrations below WHO permissible limits for pharmaceuticals.

3. Toxicological Studies

Experimental animal studies provide mixed findings:

- Safe outcomes were reported for *Swarna Bhasma* and *Abhraka Bhasma*, with no organ toxicity observed at therapeutic doses.
- Chronic administration of *Rasasindura* did not induce significant nephrotoxicity or hepatotoxicity when prepared according to classical methods.
- Conversely, formulations lacking proper Shodhana showed toxic changes, underscoring the importance of processing.

These results suggest that toxicity is not inherent to metals in Ayurveda but linked to improper preparation or overdosing.

4. Clinical Safety Reports

Several clinical studies and case series document the safe therapeutic use of herbo-mineral formulations:

- *Swarna Bhasma* in pediatric immunomodulation trials demonstrated enhanced immunity without adverse events.
- *Makaradhwaja* and *Rasasindura* were reported to improve outcomes in rheumatoid arthritis and neurological conditions.
- Cases of lead poisoning and mercury toxicity have been reported in the West, but investigations revealed adulteration, use of raw metals, or unregulated imports rather than GMP-certified formulations.

Thus, clinical safety data largely support Ayurveda's claim of safety when formulations are prepared traditionally.

5. Causes of Reported Toxicity Cases

Analysis of toxicity reports reveals:

- Lack of Standardization: Commercial preparations not adhering to classical methods.
- Poor Manufacturing Practices: Use of raw metals without detoxification.
- Unregulated Exports: Products sold without proper labeling or regulatory checks.
- Self-medication & Overdosing: Use without physician supervision.

These factors contribute more to toxicity than the Ayurvedic principles themselves.

6. Regulatory and Global Perspectives

WHO and Ministry of AYUSH stress GMP and quality assurance. Guidelines emphasize heavy metal testing, batch-wise documentation, and certification. Global regulatory bodies remain skeptical, primarily due to sporadic toxicity reports, highlighting the need for stronger pharmacovigilance.

DISCUSSION

The controversy surrounding heavy metals in Ayurveda lies at the intersection of traditional pharmaceutics and modern toxicology. From a scientific standpoint, toxicity depends on the chemical form, dose, and bioavailability of metals. Ayurveda anticipated this through purification and calcination methods, ensuring safe transformations[16].

Modern evidence supports this rationale: sulfide and oxide forms of metals in *Bhasmas* show reduced solubility and toxicity compared to raw forms. Nano-scale particle formation may enhance targeted bioavailability, offering therapeutic effects at micro-doses. This contrasts sharply with the toxicity profile of soluble salts studied in environmental toxicology, which are often incorrectly extrapolated to Ayurvedic formulations[17].

However, challenges persist. The lack of universal standardization in preparation methods creates variability. While academic and GMP-certified pharmacies adhere to classical methods, unregulated markets sometimes bypass critical detoxification steps, leading to safety concerns. Global case reports often stem from such malpractice[18].

Another gap is limited large-scale clinical trials. Most evidence derives from small cohorts or animal studies. Rigorous randomized controlled trials (RCTs) evaluating both efficacy and safety are essential for global acceptance[19].

Future prospects include[20]:

- Development of pharmacopeial standards with defined limits for heavy metals.
- Bridging traditional *Shodhana* methods with nanoscience to explain transformations.
- Educating practitioners and consumers about safe usage and risks of unregulated products.

Thus, Ayurveda's use of heavy metals should not be dismissed as unsafe. Instead, it should be seen as a sophisticated pharmaceutic system requiring quality assurance, modern validation, and responsible dissemination.

CONCLUSION

Heavy metal concerns in Ayurvedic formulations are often misrepresented as inherent flaws, when in reality they stem from deviations in preparation, poor regulation, and lack of scientific understanding. Traditional Ayurvedic pharmaceutics incorporates elaborate detoxification and transformation methods that convert toxic raw metals into therapeutically safe compounds. Analytical and toxicological studies confirm that such preparations differ significantly from raw heavy metals in terms of structure, solubility, and bioavailability.

Clinical evidence further supports their safety when used in appropriate doses under professional supervision. Reported toxicity cases are overwhelmingly linked to improper manufacturing, adulteration, or misuse rather than classical Ayurvedic practice.

To ensure global credibility, Ayurveda must prioritize GMP compliance, pharmacopeial standardization, and advanced safety evaluations. Integration of traditional methods with modern nanoscience and pharmacology offers a promising path forward. Ultimately, dispelling myths and providing scientific clarifications can restore confidence in Ayurvedic herbo-mineral formulations, enabling them to serve as valuable tools in integrative medicine.

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