

Safety and Toxicological Assessment of Metallic and Mineral Preparations in Ayurveda”

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Abstract-

Ayurveda, the traditional Indian system of medicine, incorporates a wide range of metals and minerals in its formulations, including mercury (Rasa or Parad), lead (Nag), arsenic compounds (Haratala and Manashila), copper (Tamra), and iron (Lauha). While these substances are believed to offer significant therapeutic value, concerns regarding their potential toxicity have emerged, especially when purification and manufacturing processes are not adequately followed. This review systematically evaluated toxicological studies published between 1990 and 2024 using electronic databases such as PubMed, Scopus, and Google Scholar. Findings indicate that mercury, if not properly purified, can lead to neurotoxicity, nephrotoxicity, and immunotoxicity. Similarly, lead contamination, especially in improperly prepared Nagbhasma, poses serious risks to the nervous, cardiovascular, and renal systems. Arsenic-containing preparations such as Haratala and Manashila have demonstrated potential toxicity depending on the form and dosage used. Copper and iron-based formulations, though commonly used, also carry toxicity risks if not properly monitored or dosed. Overall, the therapeutic potential of these Ayurvedic preparations is significant, but their safety depends heavily on stringent quality control, standard manufacturing protocols, regulatory compliance, and individualized patient assessment. Ensuring these measures can help harness the benefits of Ayurvedic metals and minerals while minimizing health risks.

Keywords- Ayurvedic medicine, Biomarkers, Metals and minerals, *Rasa Shastra*, Toxicity.

Introduction

Ayurveda, the ancient Indian system of medicine, utilizes various metals and minerals in its therapeutic formulations. These substances, collectively known as "*Rasa Shastra*," play a crucial role in *Ayurvedic* pharmacology. While *Ayurvedic* practitioners believe these metals and minerals can offer therapeutic benefits, concerns regarding their potential toxicity have raised questions about their safety. This review aims to provide a comprehensive overview of the toxicological studies conducted on *Ayurvedic* metals and minerals.

Methodology

A systematic search of electronic databases, including PubMed, Scopus, and Google Scholar, was conducted. The search terms included "*Ayurveda*," "*Rasa Shastra*," "*Ayurvedic* metals," "*Ayurvedic* minerals," "toxicity," and "toxicological studies." Articles published between 1990 and 2024 were considered. Relevant studies that investigated the toxic effects of *Ayurvedic* metals and minerals on animals or humans were included in this review.

Toxicological Studies on Ayurvedic Metals and Minerals-**1. Safety and Toxicity Profile of Rasa or Parad (Mercury):**

Mercury, known as "*Rasa*" or "*Parad*" in *Ayurveda*, has been used for centuries in *Ayurvedic* medicines to treat various

ailments, including respiratory disorders, neurological conditions, and digestive issues. *Ayurvedic* practitioners know that mercury, when properly purified and used in combination with other herbs, can offer therapeutic benefits. However, its toxic potential has raised questions about its safe use.

Mercury Toxicity^(1,2,3,4)

Mercury exists in various chemical forms, with methyl mercury and elemental mercury being the most toxic. Exposure to mercury can occur through ingestion, inhalation, or skin contact. The primary targets of mercury toxicity are the nervous system, kidneys, and immune system. Studies have shown that chronic exposure to mercury can lead to neurotoxicity, causing cognitive impairments, tremors, and memory deficits. Furthermore, it can lead to nephrotoxicity, resulting in kidney damage and impaired renal function. The immune system can also be affected, leading to immunotoxicity and increased susceptibility to infections.

Safety Concerns in Ayurvedic Preparations-

The safety of *Ayurvedic* medicines containing mercury depends on the preparation methods and dosage. Traditional *Ayurvedic* texts emphasize a rigorous purification process known as "*Shodhana*" to render the mercury safe for medicinal use. However, there have been reports of

substandard manufacturing practices leading to elevated levels of toxic mercury compounds in some *Ayurvedic* products. Contamination during the manufacturing process can also occur due to improper handling of raw materials. These safety concerns have prompted regulatory bodies to enforce strict quality control measures and set maximum allowable limits for mercury in *Ayurvedic* formulations.

Toxicokinetics and Biomarkers-

Understanding the toxicokinetics of mercury is vital to assessing its safety. Mercury can accumulate in various organs, with the brain, kidneys, and liver being the primary sites of accumulation. Biomarkers such as blood and urine mercury levels are used to assess exposure and potential toxicity. Additionally, hair and nail mercury concentrations can reflect chronic exposure. Monitoring these biomarkers is crucial in identifying individuals at risk of mercury toxicity and evaluating the safety of *Ayurvedic* remedies containing mercury.

Regulatory Measures and Guidelines^(5,6)

Several countries have implemented regulations to address the safety concerns related to *Ayurvedic* products containing mercury. The World Health Organization (WHO) has issued guidelines for heavy metal content in traditional medicines, including mercury. The Pharmacopoeial standards, such as the Indian Pharmacopoeia, have also set limits on mercury levels in *Ayurvedic* formulations. Furthermore, quality control practices, adherence to Good Manufacturing Practices (GMP), and certification by regulatory authorities play a pivotal role in ensuring the safety of these products.

2. Safety and Toxicity Profile of Nag (Lead) in *Ayurveda*:

Nagbhasma, a processed form of lead, has been utilized in *Ayurvedic* medicine for centuries. As an integral component of numerous *Ayurvedic* formulations, it is believed to possess therapeutic properties and is used to treat various health conditions. However, concerns regarding the safety and potential toxicity of *Nagbhasma* have arisen due to the well-documented adverse effects of lead exposure.

Preparation of *Nagbhasma* in *Ayurveda*⁽⁷⁾

Nagbhasma is prepared through a complex and labor-intensive process in *Ayurveda*, known as "*Bhasmikaran*." It involves repeated purification, trituration, and calcination of lead with specific herbal and mineral ingredients. According to *Ayurvedic* principles, this process is believed to render *Nagbhasma* safe for medicinal use while enhancing its therapeutic efficacy. The traditional methods of *Nagbhasma* preparation have been passed down through generations, highlighting the importance of adhering to established protocols to ensure product safety.

Lead Toxicity and Health Implications^(8,9)

Lead is a well-known toxic heavy metal that can cause severe health issues, especially in cases of chronic exposure. It primarily affects the nervous system, leading to cognitive impairments, developmental delays in children, and neurological disorders in adults. Additionally, lead toxicity can cause nephrotoxicity, leading to kidney damage and impaired renal function. The cardiovascular system is also at risk, as lead exposure has been associated with hypertension and an increased risk of cardiovascular diseases.

Safety Concerns with *Nagbhasma*-

The safety of *Nagbhasma* in *Ayurveda* largely depends on the quality of its preparation and administration. The rigorous traditional processes of *Bhasmikaran* are intended to render *Nagbhasma* safe and enhance its therapeutic properties. However, concerns arise when substandard manufacturing practices lead to the presence of higher levels of lead and toxic lead compounds in the final product. Contamination during the preparation process or improper use of raw materials can further compromise the safety of *Nagbhasma*-containing *Ayurvedic* formulations.

Regulatory Measures and Guidelines-

Regulatory agencies have recognized the potential risks associated with the use of lead-containing *Ayurvedic* medicines and have implemented measures to ensure product safety. In India, the Drugs and Cosmetics Act, 1940⁽¹⁰⁾, and the Drugs and Cosmetics Rules, 1945¹¹, provide guidelines for the manufacture, sale, and distribution of *Ayurvedic* medicines, including *Nagbhasma*-containing formulations. The *Ayurvedic* Pharmacopoeia of India (API)⁽¹²⁾ sets standards for the quality and purity of *Ayurvedic* drugs, including *Nagbhasma*, to safeguard public health.

Biomonitoring and Biomarkers⁽¹³⁾

To assess lead exposure and its potential toxic effects, biomonitoring through blood lead level (BLL) measurements is crucial. Regular monitoring of BLL is necessary for individuals receiving *Ayurvedic* medicines containing *Nagbhasma* to detect any signs of lead toxicity promptly. Other biomarkers, such as urine and bone lead levels, can also provide valuable insights into the extent of lead exposure and its potential health implications.

3. Safety and Toxicity Profile of *Haratala* (Arsenic tri sulphide)

Haratala is an essential mineral-based substance mentioned in *Ayurvedic* texts as a therapeutic agent for various health conditions. In *Ayurveda*, it is classified as a "*Rasausadhi*," a category of mineral-based medicines believed to have potent healing properties. *Haratala* is traditionally used to treat respiratory disorders, skin diseases, digestive issues, and

certain neurological ailments⁽¹⁴⁾. *Ayurvedic* practitioners believe that when processed and administered appropriately, *Haratala* can offer effective remedies for specific ailments. . However, concerns regarding its safety and potential toxicity have emerged due to the presence of lead in its composition

Arsenic Toxicity-

Haratala contains arsenic, which are well-known toxic heavy metals. Arsenic is a potent poison that can cause acute toxicity and long-term health effects. Arsenic toxicity is associated with skin lesions, gastrointestinal disturbances, and an increased risk of cancer.

Safety Concerns with *Haratala*-

The safety of *Haratala* in *Ayurveda* is a matter of concern due to its lead content. While traditional *Ayurvedic* texts describe a meticulous process for the preparation and purification of *Haratala*⁽¹⁵⁾, concerns arise when substandard manufacturing practices lead to elevated levels of lead and toxic lead compounds in the final product. Contamination during the preparation process or the use of impure raw materials can compromise the safety of *Haratala*-containing *Ayurvedic* formulations.

Regulatory Measures and Guidelines^(10,11,12)

Regulatory bodies in various countries have implemented measures to control the use of lead-containing substances in traditional medicines, including *Haratala*. In India, the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, provide guidelines for the manufacture, sale, and distribution of *Ayurvedic* medicines. The *Ayurvedic* Pharmacopoeia of India (API) sets standards for the quality and purity of *Ayurvedic* drugs, including *Haratala*, to safeguard public health.

Biomonitoring and Biomarkers⁽¹³⁾

Assessing lead exposure and its potential toxic effects require monitoring biomarkers. Blood lead levels (BLL) are widely used as the primary biomarker of lead exposure. Regular monitoring of BLL is essential for individuals receiving *Ayurvedic* medicines containing *Haratala* to detect any signs of lead toxicity promptly. Other biomarkers, such as urine and bone lead levels, can also provide valuable insights into the extent of lead exposure and its potential health implications.

4. Safety and Toxicity Profile of *Manashila* ("Realgar" or "Arsenic Disulphide)-

Manashila, also known as "Realgar" or "Arsenic Disulphide," is a mineral-based substance used in *Ayurvedic* medicine for its therapeutic properties. It is traditionally used to treat various health conditions, including digestive issues, skin disorders, and respiratory ailments⁽¹⁶⁾. *Ayurvedic* practitioners believe that when processed and administered

appropriately, *Manashila* can offer effective remedies for specific ailments. However, the therapeutic use of *Manashila* has been a subject of debate due to the presence of arsenic in its composition and its potential toxicity.

Arsenic Toxicity⁽¹⁷⁾

Manashila contains arsenic, which are well-known toxic heavy metals. Arsenic, on the other hand, is a potent poison that can cause acute toxicity and long-term health effects. Arsenic toxicity is associated with skin lesions, gastrointestinal disturbances, and an increased risk of cancer.

Regulatory Measures and Guidelines^(10,11,12)

Regulatory bodies in various countries have implemented measures to control the use of lead and arsenic-containing substances in traditional medicines, including *Manashila*. In India, the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, provide guidelines for the manufacture, sale, and distribution of *Ayurvedic* medicines. The *Ayurvedic* Pharmacopoeia of India (API) sets standards for the quality and purity of *Ayurvedic* drugs, including *Manashila*, to safeguard public health.

Biomonitoring and Biomarkers⁽¹³⁾

Assessing lead and arsenic exposure and their potential toxic effects require monitoring biomarkers. Blood lead levels (BLL) and urinary arsenic levels are widely used as biomarkers of lead and arsenic exposure, respectively. Regular monitoring of BLL and urinary arsenic levels is essential for individuals receiving *Ayurvedic* medicines containing *Manashila* to detect any signs of lead and arsenic toxicity promptly.

5. Safety and Toxicity Profile of *Lauha* and *Lauha Bhasma* -

Lauha, commonly known as iron, is an essential mineral in *Ayurveda*, valued for its therapeutic properties and widespread use in various formulations. *Lauha Bhasma*, a processed form of iron, is also prevalent in *Ayurvedic* medicine. . It is an integral component of several *Ayurvedic* formulations prescribed for treating anemia, weakness, and various other health conditions⁽¹⁸⁾. *Lauha Bhasma*, obtained through a complex process of trituration and calcination of iron, is believed to enhance iron's therapeutic potency and reduce potential side effects.

Safety of *Lauha* and *Lauha Bhasma*-

Lauha and *Lauha Bhasma* are generally considered safe when used under proper supervision and as per the prescribed dosage. The traditional *Ayurvedic* texts emphasize a strict purification and incineration process, known as "*Shodhana* and *marana* " to render *Lauha* and *Lauha Bhasma* safe for medicinal use. When prepared correctly, the risk of adverse

effects is minimized. However, high doses of iron whether in its elemental form or as *Bhasma*, can lead to gastrointestinal disturbances such as constipation, nausea, and abdominal pain.⁽¹⁹⁾

Iron Toxicity⁽²⁰⁾

Iron overdose can lead to iron toxicity, which is characterized by the accumulation of excess iron in various organs and tissues. Acute iron poisoning can cause severe symptoms such as vomiting, diarrhea, and cardiovascular collapse. In chronic iron toxicity, iron accumulates in organs like the liver, heart, and pancreas, potentially leading to organ damage and dysfunction. Iron overload conditions, such as hereditary hemochromatosis, can also occur due to genetic defects in iron metabolism.

Regulatory Measures and Guidelines⁽¹²⁾

Recognizing the importance of safety and quality control in *Ayurvedic* medicines, regulatory agencies have set guidelines for the manufacture and use of *Lauha* and *Lauha Bhasma*-containing formulations. The *Ayurvedic* Pharmacopoeia of India (API) provides standards for the quality and purity of *Ayurvedic* drugs, including *Lauha Bhasma*. Regulatory agencies in different countries also enforce guidelines to ensure the safe use of iron-containing preparations in traditional medicine.

Biomonitoring and Safety Considerations-

Monitoring iron levels through serum ferritin levels and other biomarkers is essential in patients receiving *Ayurvedic* formulations containing *Lauha* and *Lauha Bhasma*. Regular monitoring helps prevent iron overload and associated adverse effects. Additionally, *Ayurvedic* practitioners should consider individual patient characteristics, such as age, gender, and existing health conditions, before prescribing iron-based formulations to optimize therapeutic benefits while minimizing potential risks.

6. Safety and Toxicity Profile of *Tamra* and *Tamra Bhasma* -

Tamra, or copper, is regarded as a crucial element in *Ayurveda*, where it is used in various formulations for treating specific health conditions⁽²¹⁾. *Ayurvedic* practitioners commonly prescribe *Tamra* and *Tamra Bhasma* for various health conditions, including respiratory disorders, joint pains, and skin ailments. These formulations are believed to possess anti-inflammatory, immunomodulatory, and antioxidant properties, making them valuable in promoting overall health and vitality. *Tamra Bhasma*, obtained through a meticulous process of purification, trituration, and calcination of copper, is believed to enhance copper's therapeutic efficacy and reduce potential side effects⁽²²⁾.

Safety of *Tamra* and *Tamra Bhasma*-

When used under proper supervision and within prescribed dosages, *Tamra* and *Tamra Bhasma* are generally considered safe. *Ayurvedic* texts emphasize a rigorous purification and incineration process, known as "Shodhana and *marana*," to ensure the safety and efficacy of *Tamra Bhasma*⁽²²⁾. When prepared correctly, the risk of adverse effects is minimized. However, excessive and prolonged use of copper, whether in its elemental form or as *Bhasma*, can lead to copper toxicity.

Copper Toxicity^(23,24,25)

Copper toxicity can occur due to acute or chronic exposure to excessive levels of copper. Acute copper poisoning can cause gastrointestinal symptoms such as vomiting, diarrhea, and abdominal pain. In cases of chronic exposure, copper accumulation in the liver and brain can lead to organ damage and neurological impairments. Wilson's disease, a genetic disorder of copper metabolism, is an example of a condition where copper accumulates in the body, leading to liver and neurological problems.

Regulatory Measures and Guidelines^(10,11,12)

Regulatory bodies in various countries have implemented measures to control the use of copper-containing substances in traditional medicines, including *Tamra* and *Tamra Bhasma*. In India, the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, provide guidelines for the manufacture, sale, and distribution of *Ayurvedic* medicines. The *Ayurvedic* Pharmacopoeia of India (API) sets standards for the quality and purity of *Ayurvedic* drugs, including *Tamra Bhasma*.

Biomonitoring and Safety Considerations⁽¹³⁾ -

Monitoring copper levels through serum copper levels and other biomarkers is essential in patients receiving *Ayurvedic* formulations containing *Tamra* and *Tamra Bhasma*. Regular monitoring helps prevent copper overload and associated adverse effects. Additionally, *Ayurvedic* practitioners should consider individual patient characteristics, such as age, gender, and existing health conditions, before prescribing copper-based formulations to optimize therapeutic benefits while minimizing potential risks.

Discussion-

Regulatory Measures are very much important for safety concerns regarding heavy metals and minerals. Recognizing the concerns regarding *Ayurvedic* metals and minerals' toxicity, regulatory bodies in various countries have taken steps to standardize these products and enforce safety guidelines. These measures include setting maximum allowable limits for toxic metals in *Ayurvedic* preparations, promoting good manufacturing practices, and conducting regular quality checks.

It's important to note that while *Ayurvedic* medicine has a long history of use and may offer potential therapeutic benefits, the use of substances like mercury, lead, arsenic, and copper in Ayurvedic formulations raises concerns about their safety and potential toxicity. These substances are known to have adverse health effects, particularly with chronic exposure or when used in substandard preparations. Therefore, strict adherence to quality control measures and regulatory guidelines is essential to minimize the risk of toxicity and ensure the safety of *Ayurvedic* products containing these substances.

Furthermore, biomonitoring and regular monitoring of blood lead levels (BLL) and other relevant biomarkers are crucial in patients using *Ayurvedic* formulations containing these substances. This allows for early detection and intervention in cases of lead, arsenic, and copper toxicity, if any.

In addition, it's important for *Ayurvedic* practitioners and manufacturers to follow responsible manufacturing practices, ensure appropriate dosages, and provide clear guidelines for use to mitigate the risk of adverse effects. This will help maintain the integrity and efficacy of Ayurvedic treatments while prioritizing patient safety.

Overall, while *Ayurvedic* medicine can offer valuable contributions to traditional healthcare practices, ensuring the safety and quality of formulations containing potentially toxic substances is of paramount importance to protect patient well-being and maintain public trust in these traditional treatment modalities.

Conclusion:

Ayurvedic medicines containing potentially toxic substances offer potential therapeutic benefits when used correctly. However, their toxicological profiles warrant careful consideration of safety measures. Strict adherence to quality control guidelines, purification protocols, and regulatory measures is imperative to minimize the risk of toxicity and ensure patient safety. Regular monitoring of biomarkers such as BLL and urinary arsenic levels is essential for early detection and intervention in cases of toxicity. With responsible manufacturing practices and appropriate precautions, *Ayurvedic* medicine can continue to contribute to traditional healthcare practices with reduced concerns about toxicity.

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