



REVIEW ARTICLE

Safety Concerns on Ayurvedic Herbomineral Formulations—Myth or Reality?

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ABSTRACT

Background: Ayurveda, systematically evolved science of the universe, focuses on preventing, preserving health, and curing diseases in a comprehensive way. This heritage is survived through the ages and Ministry of Ayurvedic, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) took a number of initiatives to showcase its usefulness at global levels. Exclusive and extensive use of various metals and minerals in therapeutics is an integral part in Ayurveda. But, safety and toxicity concerns in the past couple of decades opened debates in conventional community, which attempted to malign the glory of Ayurveda.

Aim: The aim of this study is to review classical concepts and published researches on metallic formulations and generate evidences inferring the effectiveness and safety of Ayurveda interventions in different pathologies.

Results: Classical Ayurveda texts are filled with comprehensive information pertaining to drug collection, storage and preservation methods, standards of raw materials, standard operative procedures for different dosage forms, quality control aspects for finished products, shelf life, posology, safety, adverse drug reactions (ADRs) on inappropriate use of medicines and their management, concurrent diet advices, etc., to avoid possible ill effects. It infers that the seers were well studied about good collection practices (GCPs), good storage practices (GSPs), good manufacturing processes (GMPs), therapeutic use of such formulations, good dispensing practices (GDPs), good agricultural and collection practices (GACPs), etc., and took maximum care in the management of diseases. To substantiate classical concepts, a good number of studies on herbomineral and metallic formulations have been conducted that have proven their safety and efficacy.

Conclusion: It can be said that rational use of Ayurvedic formulations is well established before the period of *Charaka Samhita*, more than 5,000 BC. All the safety and efficacy concerns raised in the recent past are possibly some part of conspiracy that needs to be addressed systematically.

Keywords: Herbomineral formulations, Metals, Multicentric studies, Safety, Toxicity.

Clinical significance: Besides preclinical studies, simple case studies to multicentric studies can be initiated. A

strong network of sophisticated laboratories, scientists of biotechnology, and Ayurvedic physicians can be developed.

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INTRODUCTION

Traditional systems of medicines are being utilized since thousands of years for healthcare by individuals in countries of the South-East Asia Region as well as in other parts of the world. In recent times, public interest has shifted toward traditional medicines for various concerns. They continued to be a valuable source of remedies to the people around the world to secure their health.¹ World Health Organization (WHO) also encourages, recommends, and promotes traditional medicines in national health programs because such drugs are easily available, comparatively safe, and people have faith in such remedies, and their industrial production is environment friendly.² They are attracting attention of developing countries too as an alternative or adjuvant to synthetic drugs.

The Ayurvedic Materia Medica comprises of resources of plant, animal, metal, and mineral origin,³ which have been advocated for use in different pathologies. Exclusive and extensive use of various metals and minerals in therapeutics is an integral part in this system of medicine. Often, these resources (plant, animal, metal, and mineral) are being used as ingredients of poly-herbal, herbomineral, and metallic compound formulations by the seers, who have documented their clinical experiences and passed on the knowledge to further generations. Comprehensive description of drugs, their varieties, characteristics, identification methods, guidelines toward good collection practices (GCPs), good storage practices (GSPs), good manufacturing processes (GMPs), therapeutic use of such formulations, good dispensing practices (GDPs), regulations towards specific diet and deeds during treatment, possibilities of developing adverse effects and their management, etc., is vividly available in the classical texts of Ayurveda.

Considering the potentiality and possibility of significant contribution of Ayurveda in global healthcare, the science is receiving momentum as an effective alternative

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to the conventional system of medicine by virtue of its systematic approach to cure and prevent ailments through natural resources.^{4,5} Being used for over a long period, these medicines are acknowledged as safe, which is the ultimate proof for their nontoxic beneficial effects.

However, in the past couple of decades, the use of traditional interventions including Ayurveda has raised safety, efficacy, and toxicity concerns and initiated debates in scientific conventional community.⁶⁻¹⁴ In addition to this, UN Environment Programme (UNEP) released a report Mercury—Time to Act, where imposing a ban on mercury for trade considering its effect on environment has been put forward.¹⁵ Such controversies have tried to malign the reputation of Ayurveda at global levels.

MATERIALS AND METHODS

Classical texts of Ayurveda including *Charaka samhita*, *Sushruta Samhita*, and *Ashtanga hridaya* were reviewed for classical information. Published researches available at online databases like PubMed, etc., were screened to collect information.

RESULTS

Concerns on Metal/Mineral-based Formulations (*Rasa aushadhi*)

Using processed metals/minerals, herbomineral preparations, i.e., *Rasaushadhi* in healthcare is the unique

characteristic feature in Ayurveda. Different categories of metals, minerals, and other schedule E-1 drugs being used therapeutically in the system of Ayurveda are depicted at Table 1. Various herbal or animal resources used during different pharmaceutical procedures help in converting the minerals and metals into bio-assimilable forms. Seers have prescribed specific processing techniques (*Shodhana*, *Marana*, etc., exclusively for schedule E-1 drugs and other drugs of metallic/mineral origin), which help in removing hazardous properties from these drugs. Classics have also prescribed testing methods (like *Bhasma pariksha*), which will tell the manufacturer whether the drug has attained a form, which does not have hazardous properties when used properly, i.e., with specified adjuvants and dosage prescribed by a physician. In the absence of such typical pharmaceutical procedures, there is a possibility of toxicity.¹⁶

Parada (mercury), one of such important metals, is inseparable part of Ayurveda and is used in preparation of various formulations like *Makaradhwaja*, *Rasa sindhura*, etc. Classical preoperative procedures like *Shodhana*, *Marana*, etc., are mandatorily to be followed in the pharmaceutical processes of these formulations. Such procedures are anticipated to make the metals/minerals harmless and render suitable for therapeutic use. Meticulous guidelines have been laid down in classical texts while preparing *Rasaushadhies*.¹⁷ In due course of time,

Table 1: Categorization of metals, minerals and other schedule E-1 drugs used in Ayurveda therapeutics

Category	Description	No.	Substances under the group
1 <i>Rasa</i>	The prime substance of <i>Rasa Shastra</i>	1	<i>Rasa</i> (mercury)
2 <i>Maha Rasa</i>	The next important group of minerals	8	<i>Abhraka</i> , <i>Vaikranta</i> , <i>Makshika</i> , <i>Vimala</i> , <i>Shilajatu</i> , <i>Sasyaka</i> , <i>Chapala</i> , and <i>Rasaka</i>
3 <i>Upa Rasa</i>	These are the substances next to <i>Maha Rasa</i>	8	<i>Gandhaka</i> , <i>Gairika</i> , <i>Kasisa</i> , <i>Kankshi</i> , <i>Haratala</i> , <i>Manahshila</i> , <i>Anjana</i> , and <i>Kankushtha</i>
4 <i>Sadharana Rasa</i>	Substances next to <i>Upa Rasa</i> are <i>Sadharana Rasas</i>	8	<i>Kampillaka</i> , <i>Gauripashana</i> , <i>Navasagara</i> , <i>Kaparda</i> , <i>Vahnijara</i> , <i>Girisindoora</i> , <i>Hingula</i> , and <i>Mridgara Sringa</i>
5 <i>Dhatu Varga</i>	Group of metals. Further categorized in to three subdivisions		
<i>Shuddha Loha</i>	Pure metals	4	<i>Swarna</i> , <i>Rajata</i> , <i>Tamra</i> , and <i>Loha</i>
<i>Puti Loha</i>	Metals, which emits fetid smell while processing	3	<i>Naga</i> , <i>Vanga</i> , and <i>Yashada</i>
<i>Misra Loha</i>	Alloy metals	3	<i>Pittala</i> , <i>Kamsya</i> , and <i>Varta</i>
6 <i>Ratna/Mani</i>	Precious stones. Have astrological importance in addition to their role on human health	9	<i>Manikya</i> , <i>Mukta</i> , <i>Pravala</i> , <i>Marakata</i> , <i>Pushparaga</i> , <i>Vajra</i> , <i>Indraneela</i> , <i>Gomeda</i> , and <i>Vaidhurya</i>
7 <i>Uparatna Varga</i>	Semiprecious stones	6	<i>Vaikranta</i> , <i>Suryakanta</i> , <i>Chandrakanta</i> , <i>Rajavarta</i> , <i>Pairojaka</i> , and <i>Sphatika</i>
8 <i>Sudha Varga</i>	Group of substances, which are rich calcium compounds	12	<i>Sudha</i> , <i>Khatika</i> , <i>Godanti</i> , <i>Swetanjana</i> , <i>Mrigasringa</i> , <i>Hastidanta</i> , <i>Kurmaprista</i> , <i>Kukkutanda Twak</i> , <i>Shankha</i> , <i>Shukti</i> , and <i>Shambuka</i>
9 <i>Sikata Varga</i>	Silicate compounds	4	<i>Dugdha Pashana</i> , <i>Naga Pashana</i> , <i>Kausheyashma</i> , and <i>Badarashma</i>
10 <i>Ksara Varga</i>	Substances with alkaline nature	3	<i>Tankana</i> , <i>Sarja Ksara</i> , and <i>Yava Ksara</i>
11 <i>Visha</i>	Poisonous substances	9	<i>Halahala</i> , <i>Kalakuta</i> , <i>Sringaka</i> , <i>Pradeepana</i> , <i>Saurashtrika</i> , <i>Brahmaputra</i> , <i>Haridra</i> , <i>Saktuka</i> , and <i>Vatsanabha</i>
12 <i>Upavisha</i>	Poisonous substances of less potency	11	<i>Kupeelu</i> , <i>Ahiphena</i> , <i>Jayapala</i> , <i>Dhattura</i> , <i>Bhanga</i> , <i>Gunja</i> , <i>Bhallataka</i> , <i>Arka</i> , <i>Snuhi</i> , <i>Langali</i> , and <i>Karaveera</i>

Note: Differences of opinions are available regarding the types and numbers of respective categories of substances. Only one version has been depicted in the table

Table 2: Synoptic outlook on *anupana*, *pathya*, *apathya* and *chikitsa* of ADRs

S. no.	Name of substance	Matra (dose)	Anupana (vehicle)	Pathya/apathya (do's/don'ts)	Chikitsa (treatment)
1	<i>Abhraka Bhasma</i> (mica)	1 Valla (Rasa Ratna Samachya 2/51)	<i>Madhu, Dugdha, Ghrita</i>	<i>Pathya</i> — <i>Kshara, Amla, Dwidala, Karkati, Vrintaka, Kareera and Taila</i> . (Rasa Jala Nidhi Vol 2, 1/30)	<i>Uma phala (Atasi)</i> rubbed with water for 3 days (Rasa Jala Nidhi Vol 2, 1/31)
2	<i>Gandhaka</i> (sulfur)	1–8 Ratti (Rasa Tarangini 8/39)	<i>Godugdha, Ghrita, Madhu</i>	<i>Apathya</i> — <i>Kshara, Amla, Lavana, Taila, Sauvira, Vidahi Anna, and Dwidala</i> , Indulgence in excessive physical stress and sexual contacts, excessive travels	<i>Milk + Ghrita</i> for 5-7 days (Rasayana Sara— <i>Parada Prakarana 102</i>)
3	<i>Haratala Bhasma</i> (orpiment)	1/4 to 1/2 Ratti (Rasa Tarangini 11/56)	<i>Madhu, Ghrita, Dugdha, Vasa Swarasa, Kantakari Swarasa</i>	<i>Pathya</i> — <i>Madhura Rasa, Saindhava Apathya—Lavana, Amla, Katu Rasa, Vahni & Atapa Sevana</i>	<i>Sharkara + Madhu + Jiraka</i> TDS, <i>Madhu + Kushmanda Swarasa</i> TDS, <i>Ajaji + Sharkara, Yava Kshara + Kushmanda Swarasa</i> for 3 days (Rasa Jala Nidhi vol 2, 2/141)
4	<i>Suvarna Bhasma</i> (gold)	1/8 to 1/4 Ratti (Rasa Tarangini 15/81)	<i>Dugdha, Ghrita</i>	<i>Pathya</i> — <i>Dugdha, Sharkara, Snigdha anna, etc., Apathya—Bilwa phala, Kakarashtaka</i> (Rasendra Chudamani 14/25)	<i>Haritaki Churna + Madhu</i> for 3 days (Brihad Rasa Raja Sundara, <i>Swarna prakarana khanda 1, p 64</i>)

exclusive techniques have been developed with an intention to prepare more bio-assimilable forms of metals/minerals. Great care has been imposed while using metallic preparations in therapeutics.¹⁸ These preparations are to be administered orally in specified quantities with great caution along with requisite *Anupana* (vehicles) like *Ghrita* (ghee), *Dugdha* (milk), *Madhu* (honey), *Haritaki* (*Terminalia chebula*), *Agastya* (*Sesbania grandiflora*), *Sita* (sugar), *Dhanyaka* (*Coriandrum sativum*), etc. Besides *Anupana*, exclusive regulations in terms of *Ahara* (diet) and *Vihara* (deeds) have also been imposed during the treatment period, as briefed in Table 2. In the absence of *Anupana* and other classical posological considerations, adverse reactions are likely to happen.¹⁹

In susceptible cases of toxicity, drugs are to be withdrawn for 1 or 2 or 3 days and then treatment can be continued.²⁰ Treatment for all such occurrences of toxicity is also mentioned in the classics.

The science is filled with concepts pertaining to drug administration. A few such approaches are provided in Table 3 that reveal the vision of the seers toward possible posological considerations, pharmacokinetics, and dynamics of various categories of formulations.

Regular Caution while Using Ayurveda Formulations

All the preparations are not recommended for all the patients. Ayurveda considers various factors before administering a drug. The indications, dose, to whom to administer and to whom not to administer, what should be the vehicle, what are the diseases, where they are not recommended, etc. are major factors and

extremely well described in classical texts. Qualified Ayurveda physician should consider these factors before they recommend any medicine in patients.^{21,22} Right drug at the right dose by the right route at the right time for the right person will always provide beneficial effects.²³ Increased morbidity, risk of unwanted effects, etc., have repeatedly been attributed with irrational drug use.²⁴

WHO also considers irrational use of medicines (overuse, underuse, or misuse) as a major problem in widespread health hazards.²⁵ This aspect has been considered by the pioneers of Ayurveda in addition to other possible ways by which toxicity, untoward effects can occur and provided all guidelines to avoid such occurrences. Even, if in any eventuality, some untoward effects are noticed due to noncompliance of code of conduct, the treatment procedures for such conditions have also been prescribed (Table 2).

Table 3: Concepts pertaining to drug administration

	Concept	Reference
1	Importance of drug examination	Kashyapa Khila 3/111
2	Form of the drug	Charaka Sutra 4/7
3	Knowledge of side effects	Kashyapa Khila 3/28
4	Persistent use of drugs	Kashyapa Khila 3/58-60
5	Post medication precautions	Kashyapa Khila 3/65
6	Care to be taken in emaciated patients, etc.	Kashyapa Khila 3/116
7	Dose fixation	Astanga Hridaya Kalpa Siddhi 6
8	Effect of administering in excess or less dose	Kashyapa Khila 3/115

Studies that have Proven Efficacy

There are good numbers of studies that have proven significance of Ayurvedic formulations in managing various disorders, where no satisfactory treatment is available in conventional system of medicine. A first-ever, double blind, randomized, placebo-controlled pilot study comparing Ayurveda, methotrexate, and their combination, with approximately equivalent efficacy has been reported.²⁶ Formulations like *Chandraprabha vati* in diabetes,²⁷ *Garbhachintamani rasa* in lipid disorder,²⁸ *Arogyavardhini vati* in hepatic ailments,²⁹ *Rasa sindhura* as Rasayana and metabolic deficit reversal agent,^{30,31} *Makaradhwaja* in rheumatoid arthritis and as an antistress agent,^{32,33} *Rajata bhasma* as an hypnotic and analgesic agent,^{34,35} *Sameerapannaga rasa* in bronchial asthma,^{36,37} and *Yashada bhasma* in diabetes³⁸ have been established. Formulations like *Swasa kuthara rasa*, *Smriti sagara rasa*, *Swarnamakshika bhasma*, *Hridayarava rasa*, and *Tamra bhasma* are reported to be free from genotoxic potential.³⁹⁻⁴² Though mercury is said to be a potent neurotoxin, *Rasa sindhura* and *Kajjali* are proven to be safe and free from toxicity on the Zebra fish behavior model.⁴³ All such studies on Ayurvedic formulations provided leads, emphasizing safety, efficacy, and usefulness of traditional systems of medicines. A few more such evidences are given in Table 4.

Proven Facts

Absorption, distribution, and excretion of all metallic compounds vary based on the chemical forms. Absorption of inorganic compounds of mercury in human body is poor on oral administration (10–15%), while organic mercurial compounds absorb more than 90%. In addition, organic mercurials cross blood–brain barrier and blood–placental barrier, hence, they are more fatal.⁴⁴ Interestingly, many studies on Ayurvedic mercurial preparations have proven the chemical nature of the finished products to be inorganic (mostly sulfides).⁴⁵ Further, traditionally prepared mercurials are proven to be different from industrial mercurials and supported safety of such medicines.⁴⁶ Researches also established that cinnabar is not converted into methylmercury by human intestinal bacteria, thus, safe for human administration.⁴⁷

CONCLUSION

A drug can be panacea or poison. A drug satisfying the criteria of a standard drug will always become panacea, if it is used properly. On the other hand, a poorly prepared or manufactured drug, however, used skillfully, will always prove to be a poison. Importance of Ayurveda in global healthcare cannot be denied at any platform.

To showcase the actual potentiality, visionary pioneers have proposed of developing a strong networking in between sophisticated laboratories and Ayurvedic physicians. At the same time, they suggested of understanding chemical nature of the finished traditional products being administered in therapeutics, educating regulatory authorities, and consumers about the facts of basic traditional concepts that can help in differentiating myth and reality.⁴⁸

In addition to this

- The actual effectiveness of Ayurveda is to be disseminated through systematically designed researches. Though RCTs are undisputed gold standards in researches of synthetic drugs, as such, they cannot be applied to Ayurveda. Approaches like whole body systems, multiphase optimization strategy (MOST), strengthening the reporting of observational studies in epidemiology (STROBE), etc., are to be attempted in researches that include Ayurveda drugs.
- Simple case studies to multicentric studies can be initiated at least for noncommunicable diseases to show the potentiality of Ayurveda in providing satisfactory results.
- Regulation of private AYUSH practices and accrediting mechanism at regular intervals may be thought of.
- Empowering the farmers and villages with good cultivation, good agriculture practices. AYUSH Gram Yojana, the one initiated in Madhya Pradesh, may be revived and expanded to all states.

Shortcomings of previous studies that raised safety concerns are as follows:

- Conventional scientists were not aware of traditional principles of patient examination, evaluation, and art of drug administration.
- In most of the western studies, metallic drugs were subjected to chemical examination using standards applied in modern medicine, focusing only on the metallic content. No works are accounted on clinical or pharmacological aspects by them. The chemical forms of the metallic preparations were never thought to be attempted.
- The number of cases with adverse reactions with the use of Ayurveda preparations is very few worldwide against the use of thousands of consumers. While reports with synthetic drug molecules are very frequently being published throughout the world. In such instances, blaming the traditional practices or metallic preparations is not appropriate.
- In a few cases, the medicines are being purchased as over the counter or through Internet. This practice is not applicable in the practice of Ayurveda. This also indicates the trend of self-medications.

Table 4: Proven safety and efficacy of few ayurvedic formulations

Intervention	Activity	Result	Reference
1 Swarna bhasma	Protein adsorption, blood compatibility and complement activation potential in Caco-2 cell line along with its physicochemical characterization	Particles were noncytotoxic	Paul W, Sharma CP. Blood compatibility studies of Swarna bhasma (gold bhasma), an Ayurvedic drug. <i>Int J Ayurveda Res</i> 2011 Jan;2(1):14-22.
2 Mahayograj Guggulu	Heavy metal estimation and safety studies in Charles foster strain Albino rats	Safe at tested dose levels	Lavekar GS, Ravishankar B, et al. <i>Int J Ayurveda Res</i> 2010;1(3):150-158
3 Jasada bhasma	Safety and bioactivity studies of Jasad Bhasma and its in-process intermediate in Swiss mice	No bio-accumulation of zinc in major organs No deleterious effect on kidney and liver	Chavare A, Chowdari P, et al. <i>J Ethno pharmacol</i> 2017;197:73-86
4 Black Shilajit	Evaluation of its safety profile after 91 days repeated administration in albino rats	No significant change was found in iron level of treated groups. It is safe for long-term use as a dietary supplement	Velmurugan C, Vivek B, et al. <i>Asian Pac J Trop Biomed</i> 2012;2(3):210-214
5 Lauha Bhasma	Acute and subacute toxicity study in Albino rats	It was found to be safe at the therapeutic dose and also at five times the therapeutic dose levels	Joshi N, Dash MK, et al. Toxicity study of Lauha Bhasma (calcined iron) in albino rats. <i>Ancient Sci Life</i> 2016;35:159-166
6 Immuforte—an Ayurvedic immunostimulant formulation	Subchronic safety evaluation in Holtzman rats in reverse pharmacology	It does not cause any observable toxicity up to dose used in the study (600 mg/kg) administered for the period of 90 days and is safe for the human use	Dhumal R, Patil P, et al. Sub-chronic safety evaluation of ayurvedic immunostimulant formulation 'immuforte' in rats in reverse pharmacology. <i>Toxicol Int</i> 2013;20:87-94
7 Basanta Kusumakara Rasa	Evaluation of their safety on neurobehavioral activity and oxidative stress in male Wistar rats	No significant changes in cognitive and motor functions and biochemical parameters in doses equivalent to the human dose demonstrates the safety of metal based Ayurvedic formulations	Kumar G, Gupta Y. Evidence for safety of Ayurvedic herbal, herb-metallic and Bhasma preparations on neurobehavioral activity and oxidative stress in rats. <i>Ayu</i> 2012;33(4):569-575
8 Ayurvedic herbo-metallic preparations containing gold, iron, and mercury	Total 10 clinical studies showing their safety and efficacy in pediatric disorders were compiled	These preparations were found quite safe and effective in chronic pediatric disorders such as sickle cell anemia and seizure with proper dose and adjuvant	Shingadiya RK, Chaudhary S, et al. Evidence-based safety and efficacy of Ayurvedic herbo-metallic preparations containing gold, iron, and mercury with special reference to pediatrics. <i>Med J DY Patil Univ</i> 2017;10:222-228
9 Makaradhwaja	Ninety days repeated dose oral toxicity	No adverse effect on body weights, feed consumption and biochemical parameters was observed on administration of 10 therapeutic equivalent dose (TED) level. There was no treatment-related changes observed in the histopathological evaluation at dose level 10 TED	Jamadagni S, Jamadagni PS, et al. Ninety days repeated dose oral toxicity study of Makaradhwaja in Wistar rats. <i>Ayu</i> 2017;38:171-178
10 Rasamanikya	Acute and chronic toxicity	The dose of 2,000 mg/kg did not produce any observable toxic effects or mortality in acute toxicity Safety of Rasamanikya at therapeutic and five-fold therapeutic dose level has been revealed in the chronic toxicity study. Mild to moderate pathological changes on different hematological, serum biochemical and cytoarchitecture of different organs were observed at 10-fold therapeutic dose level. Based on these observations, it can be concluded that Rasamanikya is safe at therapeutic dose levels when used judiciously along with specified adjuvants	Chaudhari SY, Biradar S, et al. Acute and Chronic Toxicity of Rasamanikya, an Ayurvedic Arsenical Formulation in Rats. <i>Indian J Pharm Sci</i> 2018;80(2):325-333

- Another important issue is the nonavailability of baseline data for the heavy metals. There is always a possibility that the observed heavy metals in the product may have entered into the product through cross-contamination or they may enter into the system of the consumer as contaminants through food or water.

In all such instances, one cannot raise a safety or efficacy concern and blame a drug or a system. It needs a thorough examination of different factors before coming to a conclusion.

Thus, it can authentically be said that comprehensive information is available in classical Ayurvedic literature reflecting that the pioneers of Ayurveda have well-documented specific processing techniques, therapeutic dosage, and concurrent diet advice to avoid any ill effects along with treatment procedures for any complications that may arise due to irrational use of medicines.

In such circumstances, statements like Ayurvedic drugs are hazardous are nothing but ignorance about the age old science. Hence, a person who is unaware of such classical techniques, i.e., *Shodhana*, *Marana*, etc., only can raise concerns over the safety issues.

All this information leaves no doubt that the seers of Ayurveda were well versed with the pharmacokinetics and pharmacodynamics of metallic preparations. They took precautions to avoid any harmful effects resulting from their use in therapeutics.⁴⁹ Safe dosages were codified. Suitable *Anupana* (adjuvants) and dietary advises were recommended along with specific antidotes and treatments for any complication.

To conclude, it can be said that rational use of Ayurveda formulations is well established before the period of *Charaka Samhita* (more than 5,000 BC) which is evident from the clear descriptions available in the classic. This was the period when a greater part of the nations on the planet were just awakening.⁵⁰ Looking into the glorious heritage, evidences through the classical literatures, current practices, and pre-clinical observations, it can be authentically and strongly said that Ayurveda is boon to the ailing population.

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हिंदी सारांश

आयुर्वेदिक पादप-खनिज औषधयोगों की सुरक्षा संबंधी चिंता - मिथक या सत्य ?

पृष्ठभूमि: आयुर्वेद विश्व का व्यवस्थित रूप से विकसित विज्ञान है, जो व्यापक रूप से निवारण, स्वास्थ्य संरक्षण और रोगों का उपचार करने पर केंद्रित है। यह धरोहर युगों से बची हुई है और आयुर्वेद, योग और प्राकृतिक चिकित्सा, यूनानी, सिद्ध और होमियोपैथी (आयुष) मंत्रालय ने इसकी उपयोगिता को वैश्विक स्तर पर दर्शाने के लिए अनेक बार पहल की है। आयुर्वेद उपचार में विभिन्न धातुओं और खनिजों का विशिष्ट और विस्तारित प्रयोग एक अभिन्न अंग है। परंतु, पिछले कुछ दशकों से सुरक्षा और विषाक्तता पर पारंपरिक समुदाय ने बहस छेड़ दी है, जिसने आयुर्वेद की प्रतिष्ठा को नुकसान पहुंचाने का प्रयास किया है।

उद्देश्य: अध्ययन का उद्देश्य धातु औषधयोगों पर शास्त्रीय धारणाओं तथा प्रकाशित अनुसंधानों की समीक्षा करना, साक्ष्य उत्पन्न करना है, जिससे विभिन्न रोग-निदानों में आयुर्वेद की प्रभावशीलता व सुरक्षा को प्रमाणित किया जा सके।

समीक्षा परिणाम: शास्त्रीय आयुर्वेद ग्रंथ औषध एकत्रण, भंडारण और संरक्षण पद्धतियों, कल्पनाओ कच्चे माल के मानक, मानक संचालन पद्धतियों, तैयार उत्पादों हेतु गुणवत्ता नियंत्रण दृष्टिकोण, शेल्फ लाइफ, पोसोलोजी, सुरक्षा, औषधि के अनुचित प्रयोग और प्रबंधन से प्रतिकूल औषध प्रभाव (एडीआर), अनुवर्ती आहार संबंधी सलाह, आदि विस्तृत सूचनाओं से भरा पड़ा है ताकि प्रतिकूल प्रभावों की संभावना को रोका जा सके। यह प्रमाणित करता है कि आचार्यों ने ऐसे औषधयोगों का गुड कलेक्शन प्रेक्टिस (जीसीपी), गुड स्टोरेज प्रेक्टिस (जीएसपी), गुड मैनूफैक्चरिंग प्रोसेसिस (जीएमपी), उपचारात्मक प्रयोग, गुड डिस्पेंसिंग प्रेक्टिस (जीडीपी), गुड एग्रीकल्चर और कलेक्शन प्रेक्टिसिस (जीएसपी) आदि का अच्छा अध्ययन किया था तथा रोगों के प्रबंधन में अधिकतम ध्यान दिया। शास्त्रीय धारणाओं की पुष्टि करने हेतु, पादप-खनिज और खनिज औषधयोगों पर बड़ी मात्रा में अध्ययन किए जिन्होंने इनकी सुरक्षा और प्रभावशीलता को सिद्ध किया है।

निष्कर्ष: यह कहा जा सकता है कि आयुर्वेदिक औषधयोगों का तर्कसंगत उपयोग 5,000 ई.पू. से अधिक, चरक संहिता के समय से पूर्व भली-भाँति स्थापित हो गया था। हाल ही में उठाये गए सुरक्षा और प्रभावकारिता संबंधी सभी मामलों में कुछ साजिशों की संभावना है, जिन्हें व्यवस्थित रूप से सुलझाने की आवश्यकता है।

मुख्य शब्द: पादप-खनिज औषधयोग, धातु, बहुकेंद्रिक अध्ययन, सुरक्षा, विषाक्तता।