

CLINICAL EVIDENCE OF RASAYAUSHDHIS IN AYURVEDA: A REVIEW FROM THE PERSPECTIVE OF RASASHASTRA.

¹Dr Swapnali S. Patil,

¹Assistant Professor,

¹Rasashastra and Bhaishajya Kalpana,

¹Bhausaheb Mulak Ayurved Mahavidyalaya, Nagpur, India.

Abstract : Rasāyāushdhī, are nothing but formulations consisting of natural herbs, minerals, and metals known for their therapeutic properties. Ayurvedic medicine, aimed at enhancing vitality, longevity, and overall health. The clinical evidence supporting the efficacy of Rasāyāushdhī has gained attention in recent years, with studies highlighting their potential benefits in immunomodulation, antioxidant effects, cognitive enhancement, anti-aging, and chronic disease management. Key ingredients such as Amalaki, Ashwagandha, Brahmi, Suvarna Bhasma, Abhrak Bhama, Makshik Bhasma and Guduchi have shown promise in clinical trials for improving immune function, reducing oxidative stress, and promoting mental health. They are known for their smaller dosage and quick results. Additionally, Rasāyāushdhī are useful in the majority of difficult to cure disease conditions like diabetes, stroke etc. These medicines are also good appetizers and digestives. Also, they have a longer shelf life, neutral in tastes and are less cumbersome to administer. Despite the growing evidence, challenges such as variability in formulations, quality control, and the need for large-scale trials remain. This review underscores the need for continued scientific exploration to validate the traditional use of Rasāyāushdhī and integrate these therapies into modern healthcare practices.

Keywords: Rasayana, Rejuvenation, Longevity, Anti-aging, Immunity booster, Ayurvedic therapy.

1. INTRODUCTION-

Rasashastra is a specialized branch of Ayurveda concerned with the pharmaceutical processing and therapeutic application of metals, minerals and other inorganic substances. Rasaushadhis include Bhasma, Rasa, Gutika, Vati, Pottali and other formulations containing processed mineral or metallic ingredients.

The distinctive feature of Rasaushadhi preparation is that raw materials are not necessarily administered in their original form. Classical pharmaceutical procedures such as Shodhana and Marana are intended to transform the starting material into a therapeutically suitable preparation. Modern analytical investigations have demonstrated that such processing can substantially alter the physicochemical characteristics of the materials. For example, characterization studies of formulations such as Vasantakusumakara Rasa and Mahalaxmivilasa Rasa have identified specific mineral phases and elemental constituents after pharmaceutical processing.

Historically, Rasaushadhis have been described as medicines capable of producing therapeutic effects in relatively small doses and, in appropriate clinical contexts, relatively rapidly. However, modern evidence-based medicine requires these claims to be evaluated through reproducible clinical research.

2. CONCEPT OF CLINICAL EVIDENCE IN RASAUSHADHI-

Clinical evidence refers to evidence generated from studies involving human participants. In the context of Rasaushadhis, evidence may be considered at several levels:

1. Classical textual evidence – therapeutic indications described in Samhitas and Rasashastra texts.
2. Clinical experience – observations accumulated through Ayurvedic practice.
3. Observational clinical evidence – case series, cohort studies and hospital-based studies.
4. Comparative clinical studies – studies comparing an Ayurvedic formulation with standard treatment or another intervention.
5. Randomized controlled trials (RCTs) – studies involving random allocation
5. and predefined clinical outcomes.
6. Systematic reviews and meta-analyses – higher-level synthesis of available clinical evidence.

These levels should not be considered equivalent. Classical use and clinical experience provide important hypotheses, but they cannot substitute for adequately designed controlled clinical trials.

3. EVIDENCE FOR THERAPEUTIC EFFICACY-

3.1 Herbo-mineral formulations

One contemporary clinical example is the randomized comparative evaluation of IMMBO, an Ayurvedic herbo-mineral formulation, in allergic rhinitis. The study included 250 patients who were randomized to receive IMMBO or a combination of levocetirizine and montelukast for 28 days. The study was designed to evaluate efficacy, safety and tolerability. Such comparative randomized research is important because it moves beyond traditional claims and evaluates a formulation against an established therapeutic regimen.

A randomized placebo-controlled pilot trial also evaluated an Ayurvedic treatment regimen containing Swasari Ras along with other Ayurvedic medicines in asymptomatic COVID-19 patients. However, because the intervention was a combination regimen rather than Rasaushadhi monotherapy, attribution of the observed effects specifically to Swasari Ras is limited.

These studies demonstrate that clinical research on herbo-mineral formulations is possible, but they also highlight an important methodological issue: when several medicines are administered together, the individual contribution of a particular Rasaushadhi cannot be established with certainty.

4. PHARMACEUTICAL PROCESSING AND ITS RELEVANCE TO CLINICAL EVIDENCE-

A fundamental principle of Rasashastra is that pharmaceutical processing is central to the transformation of raw materials into medicinal preparations.

Shodhana-

Shodhana is traditionally performed for purification and processing of selected raw materials. From a contemporary perspective, the procedure may influence the chemical composition, surface characteristics and biological behaviour of the final product.

Marana-

Marana involves repeated processing and incineration to prepare Bhasma. Modern investigations have demonstrated changes in particle characteristics and mineral phases following these processes.

Bhavana-

Bhavana involves levigation with specified liquid media. It may contribute plant-derived constituents and alter physicochemical characteristics of the formulation.

Therefore, clinical evidence cannot be separated from pharmaceutical quality. A clinical trial performed with one standardized preparation cannot automatically be generalized to every commercially available product bearing the same classical name.

Modern characterization studies support the importance of this issue. For example, analytical studies of Vasantakusumakara Rasa and Mahalaxmivilasa Rasa have used techniques such as elemental analysis, HPTLC and X-ray diffraction to characterize their composition and mineral phases.

5. SAFETY EVIDENCE-

Safety is one of the most important aspects of Rasaushadhi research because some formulations contain metals or minerals such as mercury, lead, arsenic, copper, tin or iron.

The presence of an element in a formulation should not, by itself, be interpreted as evidence of toxicity or safety. The chemical form, pharmaceutical processing, dose, particle characteristics, bioavailability, duration of administration and patient-related factors are all relevant.

Preclinical research has investigated the safety of several formulations. For example, chronic toxicity studies of Shwas kas Chintamani Rasa and Kas Shwas Hari Rasa in Wistar rats reported no treatment-related toxicity at the tested therapeutic and higher doses during the study period. Such findings are useful for safety assessment but cannot be directly equated with proof of safety in humans.

Similarly, a sub-chronic toxicity investigation of Nityanand Rasa was undertaken because of concerns regarding heavy-metal-containing Ayurvedic formulations.

Human pharmacovigilance data are equally important. A prospective pharmacovigilance study in an Ayurvedic hospital documented 52 confirmed adverse drug reactions among 84 reported adverse drug events; six confirmed reactions were associated with Rasa Aushadhi. The study demonstrates the importance of systematic adverse-event monitoring in routine Ayurvedic practice.

Consequently, Rasaushadhis should be regarded as medicines requiring appropriate pharmaceutical quality control, rational indication, correct dose, duration and clinical monitoring, rather than assuming that classical origin alone establishes safety.

6. CURRENT STATUS OF CLINICAL EVIDENCE-

The available literature indicates that research on Rasaushadhis can be divided broadly into these categories:

Evidence category	Current status
Classical therapeutic descriptions	Extensive
Pharmaceutical/analytical research	Increasing
Animal and toxicological research	Increasing
Human observational studies	Available but heterogeneous
Randomized controlled trials	Relatively limited
Large multicentre trials	Limited
Long-term human safety data	Insufficient
High-quality systematic reviews	Limited for individual Rasaushadhis

A 2025 review discussing clinical evidence of Rasāyāushadhī highlighted potential areas including immunomodulation, antioxidant activity, cognitive effects, anti-aging and chronic disease management, while also identifying formulation variability, quality control and the need for large-scale trials as important challenges.

It is important, however, to distinguish Rasāyana drugs in the broad Ayurvedic sense from Rasaushadhis specifically containing processed metals/minerals. Evidence for herbal Rasayana medicines cannot automatically be used as clinical evidence for metallic or mineral-containing Rasaushadhis.

7. MAJOR LIMITATIONS OF EXISTING EVIDENCE-

Several limitations currently prevent definitive conclusions regarding the clinical efficacy of Rasaushadhis.

7.1 Small sample sizes

Many Ayurvedic clinical studies have relatively small sample sizes, reducing statistical power and generalizability.

7.2 Heterogeneity of formulations

The same classical formulation may differ according to raw-material quality, pharmaceutical procedures, number of processing cycles and manufacturing conditions.

7.3 Lack of standardized endpoints

Some studies use subjective Ayurvedic symptom scores without adequately validated or universally accepted outcome measures.

7.4 Combination therapy

Ayurvedic treatment frequently involves multiple medicines, dietary recommendations and Panchakarma procedures. While this represents real-world Ayurvedic practice, it makes it difficult to determine the independent effect of a particular Rasaushadhi.

7.5 Limited long-term safety data

Short-duration clinical studies cannot establish the safety of prolonged administration, particularly for formulations containing potentially toxic elements.

7.6 Inadequate reporting of pharmaceutical characteristics

Clinical publications should clearly report raw-material authentication, Shodhana, Marana, analytical specifications, batch numbers, elemental composition and quality-control parameters.

8. NEED FOR STANDARDIZATION-

Standardization is fundamental to generating reliable clinical evidence.

Modern characterization of Rasaushadhis may include:

- Elemental analysis
- X-ray diffraction (XRD)
- Scanning electron microscopy (SEM/FESEM)
- Particle-size analysis
- Fourier-transform infrared spectroscopy (FTIR)

- HPTLC/HPLC where applicable
- Microbial testing
- Pesticide and contaminant analysis
- Assessment of heavy-metal speciation where appropriate

For example, research on Hridayarnava Rasa has used ICP-AES, XRD, FESEM-EDAX, FTIR, thermogravimetric analysis and particle-size analysis to establish its physicochemical profile.

Such characterization should ideally accompany clinical trials so that the tested medicine is chemically and pharmaceutically identifiable.

9. RECOMMENDATIONS FOR FUTURE CLINICAL RESEARCH-

Future studies of Rasaushadhis should adopt a multidisciplinary approach integrating Rasashastra, Ayurveda, pharmacology, toxicology, analytical chemistry and modern clinical research methodology.

Important priorities include:

1. Well-designed randomized controlled trials with adequate sample sizes.
2. Prospective registration of clinical trials.
3. Clearly defined inclusion and exclusion criteria.
4. Appropriate control groups.
5. Standardized manufacturing procedures.
6. Batch-to-batch quality assessment.
7. Quantitative characterization of elemental and mineral constituents.
8. Short- and long-term safety monitoring.
9. Monitoring of hepatic, renal and hematological parameters when clinically appropriate.
10. Documentation of adverse drug reactions.
11. Transparent reporting of concomitant Ayurvedic and conventional medicines.
12. Long-term follow-up studies.
13. Independent replication of positive clinical findings.
14. Systematic reviews and meta-analyses once sufficient homogeneous trials become available.

10. CONCLUSION-

Rasaushadhis represent a distinctive and historically important pharmaceutical component of Ayurveda. Contemporary research provides evidence that several herbo-mineral formulations can be investigated through modern clinical-trial methodology, and some studies have reported encouraging therapeutic outcomes. However, the overall clinical evidence remains insufficiently comprehensive and heterogeneous to establish the efficacy and safety of Rasaushadhis as a broad therapeutic category.

The strongest future pathway is not to reject classical Rasaushadhis or accept their traditional claims without evaluation, but to investigate them systematically. Standardized pharmaceutical preparation + rigorous analytical characterization + adequately powered clinical trials + pharmacovigilance should form the foundation of modern Rasaushadhi research.

Thus, Rasashastra has an important opportunity to translate its extensive classical pharmaceutical knowledge into reproducible clinical evidence while maintaining appropriate standards of patient safety.

REFERENCES-

1. Chaudhary A, Singh N. Herbo mineral formulations (rasaoushadhies) of Ayurveda: an amazing inheritance of Ayurvedic pharmaceuticals. *Ancient Science of Life*. 2010;30(1):18–26.
2. Ota S, Singh A, Srikanth N, et al. Chemical characterization of an Ayurvedic herbo-mineral formulation – Vasantakusumākara Rasa: a potential tool for quality assurance. *Ancient Science of Life*. 2017;36(4):207–214.
3. Chemical characterization of the Ayurvedic herbo-mineral preparation Mahalaxmivilas Rasa. *Journal of Ayurveda and Integrative Medicine*. 2018.
4. Singh A, Ota S, Srikanth N, et al. Application of spectroscopic and chromatographic methods for chemical characterization of Maha Yograja Guggulu. *Journal of Evidence-Based Integrative Medicine*. 2018.
5. Pharmacovigilance study of Ayurvedic medicine in an Ayurvedic teaching hospital: a prospective survey study.
6. Sasidharan S, et al. Efficacy and safety report based on randomized controlled single-blinded multicentre clinical trial of ZingīVir-H.
7. Proof of efficacy study evaluating an Ayurvedic herbo-mineral formulation in allergic rhinitis: an open-label randomized controlled clinical trial.
8. Evaluation of chronic toxicological profile of Shwaskas Chintamani Rasa and Kas Shwas Hari Rasa.
9. Bayal MS, Zala UU, Paneliya AM. Clinical Evidence of Rasāyāushadhī. *Journal of Ayurveda and Integrated Medical Sciences*. 2025;10(3):174–177.



Copyright & License:

© Authors retain the copyright of this article. This work is published under the Creative Commons Attribution 4.0 International License (CC BY 4.0), permitting unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.