Journal of Ayurveda & Holistic Medicine

https://jahm.co.in

eISSN-2321-1563

ORA- Analytical Study

Selection of Ayurvedic Formulations for the Management of *Amlapitta* (Functional Dyspepsia) Using the RAND/UCLA Appropriateness Method: A Modified RAND/UCLA Consensus Study

[1]Vrushali Zanzad, [2*]Sunil Kumar Devaki, [3]Rajimunnisa Begam Shaik, [4]Bawadkar Prasad

ABSTRACT:

Background: Functional dyspepsia is a highly prevalent functional gastrointestinal disorder characterized by heterogeneous symptom presentation; there is limited consensus on the optimal approach for long-term management. Classical Ayurveda describes such a condition as *Amlapitta* and recommends multiple formulations for management based on the predominant *dosha*. Lack of standardized, transparent criteria in order to select specific formulations for clinical research is a major lacuna in this context. RAND/UCLA Appropriateness Method provides a structured framework for integrating available evidence with expert clinical judgment in such scenarios. **Objective**: To identify classical Ayurveda formulations considered appropriate for management of *Amlapitta* based on *dosha* specific presentations using a modified RAND/UCLA Appropriateness Method to inform future clinical research. **Methods:** A structured Modified RAND/UCLA Appropriateness Consensus was conducted. Evidence was synthesized from classical Ayurvedic texts and biomedical literature. A multidisciplinary expert panel of 9 experts independently rated the appropriateness of shortlisted formulations for *dosha*-based presentations of *Amlapitta* on a 9-point scale. Ratings were carried out over 2 rounds with discussion intervening between the rounds. Agreement, disagreement, and final appropriateness classifications were arrived at by standard RAND criteria, including median scores, inter-percentile ranges, and disagreement parameters. **Results:** 6 Ayurvedic formulations were evaluated across 3 *dosha* specific types of *Amlapitta*: *Vataja, Kaphaja* and *Vatakaphaja*. After 2 rounds of consensus, 3 combinations were classified as appropriate, 7 as uncertain while none as inappropriate. *Kamadugha Rasa, Leelavilasa Rasa* and *Shankha Vati* were rated appropriate for *Vataja, Kaphaja* and *Vatakaphaja Amlapitta* respectively, each signifying strong agreement among panelists (DI <1). **Conclusion**: RAND/UCLA Appropriateness Method application in the selection of formulations for *Amlapitta* in the current study signifies how structured expert judgement can bridge classical Ayurvedic knowledge and contemporary research standards. Implications of this approach can strengthen methodological rigor, improve standardization, and enhance the credibility of future Ayurvedic clinical trials.

KEYWORDS: *Amlapitta*, Drug Selection, Functional Dyspepsia, RAND/UCLA Appropriateness Method

RECEIVED ON:
10-01-2026

REVISED ON:
16-02-2026; 22-03-2026

ACCEPTED ON:
25-03-2026

Access This Article Online:

Quick Response Code:

Website Link:
https://jahm.co.in

DOI Link:
https://doi.org/10.70066/jahm.v14i3.2537

Corresponding Author Email:
dr.sunil.devaki@gmail.com

CITE THIS ARTICLE AS

Vrushali Zanzad, Sunil Kumar Devaki, Rajimunnisa Begam Shaik, Bawadkar Prasad. Selection of Ayurvedic Formulations for the Management of *Amlapitta* (Functional Dyspepsia) Using the RAND/UCLA Appropriateness Method: A Modified RAND/UCLA Consensus Study. Journal of Ayurveda and Holistic Medicine (JAHM) 2026; 14(3):1-14.

1. INTRODUCTION

Functional dyspepsia, a commonly found functional gastrointestinal condition encountered globally, affects approximately around 15-20% of the population. [1] Patients with functional dyspepsia develop symptoms originating from the gastroduodenal region, which are postprandial fullness, early satiety, and epigastric pain, along with epigastric burning in the absence of any structural disease. Despite a large body of literature, the pathophysiology of functional dyspepsia is not clearly understood, and a substantial proportion of patients have incomplete or no response to treatment and symptoms frequently persist on long-term follow-up. [2]

In *Ayurveda*, distinct symptom complexes in functional dyspepsia can be correlated with a clinical entity called *Amlapitta*. Derangement of the *Pitta dosha*, either in combination with *Vata* or *Kapha dosha* or both, is identified as the main pathogenic mechanism of *Amlapitta* by traditional Ayurvedic textbooks and contributes to exogenous risk factors like diet, lifestyle, and primary impairment, among others, in the digestive fire (*Agni*). Classical Ayurvedic therapeutic regimens mainly focus on correcting deranged *dosha* using highly customized dietary modifications along with Ayurvedic formulations. [3-5]

One characteristic feature of Ayurvedic therapeutics is the fact that for a given disease, *Ayurveda* offers several formulations, the selection of which usually depends upon *dosha* predominance, individual judgement, and experience of the given physician concerned. For example, in the case of *Amlapitta*, *Avipattikara Churna, Kamadugha Rasa, Shankha Vati, Leelavilasa Rasa, Sootasekhara Rasa,* and many other formulations have been described in classical treatises. Besides reflecting the individualized approach that Ayurveda follows, this therapeutic plurality also makes it difficult to translate into a methodology where standardization across individuals is needed.

Therapeutic plurality poses methodological challenge in research contexts requiring standardization despite being central to Ayurvedic clinical reasoning. For a given clinical entity, multiple pharmacologically plausible formulations are frequently indicated but rarely do classical sources identify 1 as a preferred option. Lack of explicit, reproducible criteria for choosing a given formulation in contemporary clinical research settings can result in limited transparency, reproducibility and even comparability across studies. In recent years, integrative medicine literature has brought to attention the variability in clinical practice patterns within *Ayurveda* and pressed for the development of structured clinical practice guidelines as well as standardized decision-making frameworks to improve methodological rigor- in research settings. [6] While policy level documents as well as standard treatment guidelines have been formulated [7–9], operationalized, consensus-based methods specifically designed for transparent formulation selection for *Ayurvedic* clinical research continue to remain insufficiently documented. In this situation where multiple classical options exist in absence of substantial empirical comparative evidence, exclusive dependence on conventional hierarchies of evidence may fall short. A structured method, which combines available evidence with expert clinical judgement provides is therefore required to rationalize and standardize the selection of interventions without subverting epistemological basis of *Ayurveda*.

RAND/UCLA Appropriateness Method (RAM) [10-11], developed to aid decision making in face of incomplete or heterogeneous evidence, provides such a framework. RAND systematically combines evidence synthesis along with structured expert rating, using explicit statistical criteria such as median scores and indicators of disagreement to categorize interventions as appropriate, uncertain or inappropriate for defined clinical scenarios. At the same time, it is important to note that RAM evaluates appropriateness

rather than efficacy that is, whether or not expected benefits of intervention outweigh its potential harms in a given context. This is important distinction in the case of *Ayurveda* research, where immediate objective may be rational selection of interventions for future evaluation rather than a direct comparison of therapeutic superiority.

Application of RAND/UCLA method for Ayurvedic drug selection provides a methodologically transparent approach to operationalizing classical therapeutic plurality. By translating implicit expert judgment into explicit consensus, statistically analyzable, method allows documentation of both agreement and uncertainty. Such approach may connect classical *Ayurvedic* knowledge with that of modern research standards, while maintaining its individualized clinical reasoning.

Accordingly, this study was aimed to systematically apply a modified RAND/UCLA Appropriateness Method to identify and justify *dosha* specific *Ayurvedic* formulations for the management of *Amlapitta* (functional dyspepsia), in order to develop an expert validated, evidence informed framework for formulation selection that is capable of supporting future clinical trials as well as guideline development.

RAND/UCLA Appropriateness Method [10-11] was designed to counter decision-making problems where evidence base is incomplete and also where important decisions cannot wait for further data to be collected. It combines a systematic review of evidence with structured interaction amongst experts in the form of ratings of appropriateness and application of explicit rules for determining disagreement and agreement. This method allows the transparent determination of whether or not the expected health benefit of the intervention exceeds the expected negative consequences of performing it. Current study application of RAND/UCLA Appropriateness Method in the selection of *Ayurvedic* formulations for management of *Amlapitta*. The current paper is restricted to reporting methodological process and consensus results derived from the RAND method.

Rationale for the RAND/UCLA appropriateness method: Although selection of *Ayurvedic* formulations for research or during clinical practice is partially analogous to drug selection in mainstream pharmacology, there are several key differences. Most *Ayurvedic* classical texts provide more than 1 option to treat a disease with no obvious prioritization of treatments, and there are few modern clinical studies assessing these formulations, many of which show variability in quality and methods. Interventions cannot, therefore, be selected depending on orthodox hierarchies of evidence alone. RAND/UCLA Appropriateness Method fits Ayurveda well for 3 reasons. Firstly, it specifically acknowledges the legitimacy of expert judgment when empirical evidence is not exhaustive. Secondly, RAM allows for combining heterogeneous sources of evidence, like classical textual references as well as contemporary biomedical literature. Thirdly, by having structured rating procedures and by using explicit criteria for agreement, it minimizes bias raised from dominance or informal consensus. [10-11] Importantly RAND method evaluates appropriateness rather than efficacy. Intervention is considered appropriate when expected clinical benefits outweigh potential harms within a defined clinical scenario. This is an important distinction because the main objective of this study is not to determine comparative effectiveness, but to rationalize the selection of formulations for comparative evaluation.

The uniqueness of the current study is that it is the first one in the domain to systematically apply the RAND/UCLA Appropriateness Method to Ayurvedic drug selection, transforming traditionally implicit expert judgement into a transparent and reproducible consensus process. By integrating classical Ayurvedic literature evidence along with structured expert agreement, it provides a methodologically

robust foundation for standardizing intervention selection in Ayurveda research. [12]

2. METHODS

Design of Study: This was a structured expert consensus exercise using the RAND/UCLA Appropriateness Method as illustrated in Figures 1 and 2. Process followed procedural guidance given in RAND/UCLA Appropriateness Method User's Manual [10-12] and reported in published RAND-based healthcare studies. [14-] IEC Approval number: IEC/BMK/239-2025 dated 23/06/2025, CTRI Number: CTRI/2025/12/099579, Registration date 22/12/2025, Approval date 03/01/2026

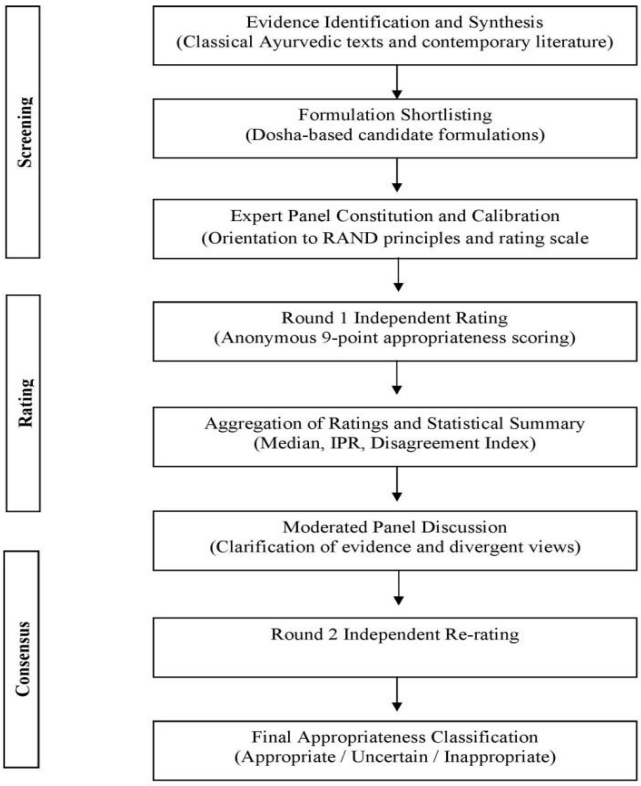

Figure 1: Flowchart of Workflow Applied in the Study

Evidence Identification and Synthesis: Narrative evidence synthesis was carried out to inform expert panel prior to rating. Relevant literature was identified through searches on PubMed/MEDLINE and Google Scholar till December 2024 using key terms including 'Functional Dyspepsia,' '*Amlapitta*,' and names of shortlisted formulations. Along with this classical *Ayurvedic* texts were also reviewed, which were *Charaka Samhita,* [5] *Madhava Nidana,* [4] *Kashyapa Samhita, Yogaratnakara*, as well as *Bhaishajya Ratnavali* [15] in order to identify traditionally indicated formulations and their *dosha*-specific rationale. Articles were screened for its relevance based on their focus on *Amlapitta*, functional dyspepsia or therapeutic use of shortlisted formulations. Purpose of this search was to generate a background evidence summary to support panel deliberation during consensus process. As objective was to inform expert discussion rather than perform a systematic review a formal PRISMA-based screening process or meta-analysis was not undertaken.

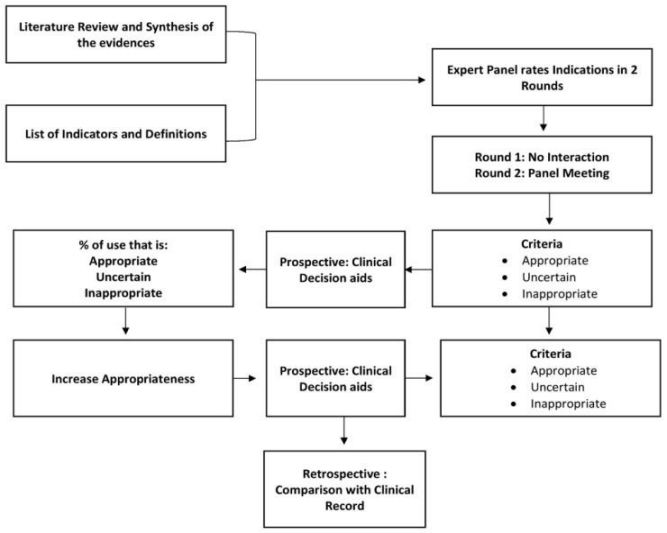

Figure 2: The RAND/UCLA Appropriateness Method

Formation and Calibration of Expert Panel: A 9-member expert panel was created using purposive sampling based on predefined eligibility criteria, including minimum of 10 years of clinical experience in *Ayurveda*, recognized clinical expertise in at least one of *Kayachikitsa*, *Rasashastra,* and *Dravyaguna,* and basic principles of *Ayurveda*. (Table 1) Also, they were from multiple academic institutions across different regions of India, in order to fulfill diversity in clinical experience and thereby minimize institutional as well as geographical and cultural bias. An international panel was not considered essential as the study focused on Ayurvedic

classical formulations primarily practiced in the Indian context. In order to maintain confidentiality as well as minimize potential influence during the consensus process expert panelists were anonymized and identified using coded identifiers (P1–P9).

Conflict of Interest Management between panel: All expert panelists were informed and requested to disclose any potential conflicts of interest related to participation. No financial or any other conflicts about evaluated formulations were reported. Panelists participated in independent as well as anonymous rating rounds in order to minimize potential bias.

Prior Orientation among Panelists: Expert panelists were oriented regarding the objectives of the study, key aspects of the RAND/UCLA method, and how to interpret the 9-point appropriateness scale, before they engaged in the rating exercise. Also, panelists underwent orientation on the RAND/UCLA scale using hypothetical clinical scenarios before Round 1. This calibration step was intended for obtaining a uniform understanding of the notion of appropriateness as much as possible and thereby decreasing the variation due to misinterpretation of the appropriateness scale. Even though standard clinical RCTs encourage blinding of interventions in present study, uniformity in the form of medication was considered essential in order to ensure consistency across panel ratings. This aspect was discussed with panelists and such homogeneity across intervention groups is accepted practice in methodological research.

Table 1: Characteristics of Expert Panel

Panellist Code	Designation and Department	Years of Clinical Experience	Academic / Clinical Role
P1	Dean, Professor & HoD, Department of *Kayachikitsa,* KAHERs Shri BMK Ayurveda Mahavidyalaya, Belagavi, Karnataka	>22 years	Academic Faculty, Researcher and Senior Clinician
P2	Professor, Department of *Kayachikitsa,* T.M.A.E.S. Ayurvedic Medical College, Nidige, Shimoga, Karnataka	>22 years	Academic Faculty and Clinician
P3	Professor & HoD, Department of *Kayachikitsa,* Shri Gurudeo Ayurveda College Gurukunj Ashram Mozari, Amravati, Maharashtra	>21 years	Academic Faculty and Clinician
P4	**Consultant, Sree Jeevana Ayurveda Vaidyasala,** Bhavanipuram, Vijayawada, Andhra Pradesh *(*Department: *Rasashastra)*	>13 years	Clinician
P5	Professor, Department of *Kayachikitsa,* Dr B.R.K.R. Government Ayurvedic College, S.R. Nagar, Hyderabad, Telangana	>20 years	Academic Faculty and Clinician
P6	Professor, Department of *Dravyaguna* S.G.V.V. Trust's Shree Jagadguru Gavisiddheshwar Ayurvedic Medical College & Hospital ,Post-Graduate Studies Research Centre , Koppal, Karnataka	>13 years	Academic Faculty
P7	Professor, Department of Basic Principles of Ayurveda*,* S.G.V.V. Trust's Shree Jagadguru Gavisiddheshwar Ayurvedic Medical College & Hospital ,Post-Graduate Studies Research Centre , Koppal, Karnataka	>15 years	Academic Faculty
P8	Professor, Department of *Kayachikitsa,* KAHERs Shri BMK Ayurveda Mahavidyalaya, Belagavi, Karnataka	>11 years	Academic Faculty and Clinician
P9	Associate Professor, Department of *Kayachikitsa,* KAHERs Shri BMK Ayurveda Mahavidyalaya, Belagavi, Karnataka	>10 years	Academic Faculty

Drafting the Ratings Statements: As *Amlapitta* is considered to be as *Pitta pradhana* (dominant) *vyadhi*, in classical context. The present study aligned with the 3 *dosha* based types of *amlapitta* as mentioned in *Madhava Nidana*, for developing rating statements for expert consensus. Each formulation shortlisted for consideration was translated to a ratings statement framed around appropriateness of its use for a specified *dosha*-based presentation of *Amlapitta*. Appropriateness was defined as a scenario in which the anticipated clinical benefits of using a given therapy at standard doses exceed its potential risk of harm, in routine practice. Cost considerations were excluded, in line with guidance provided by RAND/UCLA. As Ayurveda formulations have been said for multiple indications, the formulations were repetitive in *dosha* based subtypes of *Amlapitta* hence considered for the most appropriateness for the study.

Rating Process: RAND/UCLA rating process comprises an expert panel that independently scored appropriateness of formulations, along with a core panel that acted as moderators. Core Panel facilitated evidence presentation through methodological rigor and conducted structured discussions, but did not directly participate in scoring.

Round One Rating: Panelists independently rated each formulation through 9-point scale without interacting with other members of the panel. Ratings were submitted without names to avoid biases based on ratings from peers.

Moderated Discussion and Disagreement Handling: Summary results of round 1 (aggregate scores, medians, and measures of dispersion) were fed back to the panel, and a structured moderated discussion was undertaken. The objective of the discussion was to explore reasons why panel members had judged evidence differently and to improve.

Second-Round Rating: Panelists independently re-rated each formulation after discussion. These scores comprised the final dataset for classification.

Criteria for Agreement and Classification: Final classification depended upon median scores and assessment of agreement or disagreement using inter-percentile range (IPR) along with disagreement index (DI) as defined in the RAND/UCLA manual. Formulations with median score of 7–9 without disagreement (DI < 1) were classified as appropriate while formulations with a median score between 4–6 with disagreement (DI ≥ 1) were classified as uncertain and formulations with median score between 1–3 without disagreement were classified as inappropriate. (Tables 2 and 3, figure 3A, 3B, 3C) Some formulations were evaluated across more than one *dosha*, particularly in *Kaphaja* and *Vatakaphaja Amlapitta*. Repetition of formulations indicates their classical indication as well as clinical applicability across multiple *doshic* patterns rather than duplication or analytical error

Table 2: RAND/UCLA Appropriateness Ratings for Ayurvedic Formulations in *Amlapitta*

***Dosha* type**	**Formulations**	**Ratings from the Panelist**									**Median**	**Mean±S.D**	**IPR = (P70-P30)**	**DI**	**Agreement Level**
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**					
Vataja	*Shanka Vati*	8	7	7	8	8	7	5	8	8	8	7.11±1.22	8-7=1	0.28	Strong Agreement
	Agnisandeepani Ras	2	4	6	6	6	6	7	7	6	6	5.56±1.62	7-6=1	0.33	Strong Agreement
	Sootasekhar Ras	8	8	6	9	8	6	9	5	3	8	7.11±2.00	9-6=3	0.75	Strong Disagreement
	Kamadugha Ras	9	9	9	8	8	5	9	5	9	9	8.11±1.49	9-8=1	0.22	Strong Agreement
Kaphaja	*Leela vilas ras*	8	6	8	7	8	6	7	8	8	8	7.33±0.87	8-7=1	0.33	Strong Agreement
	Agnisandeepani Ras	8	8	5	7	7	7	9	7	5	7	7.00±1.41	8-7=1	0.29	Strong Agreement
	Sootasekhar Ras	3	9	9	9	5	7	9	7	9	7	7.33±2.19	9-7=2	0.57	Intermediate Agreement

	Kamadugha Ras	3	3	5	8	5	3	8	6	3	5	4.67±1.94	6-3=3	0.64	Intermediate Agreement
Vataka phaja	*Shanka Vati*	8	9	7	8	8	7	7	7	8	8	7.67± 0.87	8-7=1	0.25	Strong Agreement
	Agnisandeepani Ras	6	7	7	7	6	7	5	7	8	7	6.78±0.83	7-6=1	0.29	Strong Agreement
	Amlapittantaka Ras	7	7	6	9	7	6	5	7	6	7	6.56±1.33	7-6=1	0.29	Strong Agreement
	Leelavilas ras	8	8	7	8	5	6	7	6	6	7	7.00±1.07	8-6=2	0.57	Intermediate Agreement

Table 3: Interpretation of RAND/UCLA Appropriateness Scale

Score Range	Interpretation
1–3	Inappropriate (Harms outweigh benefits)
4–6	Uncertain (Balance unclear or disagreement present)
7–9	Appropriate (Benefits outweigh harms)

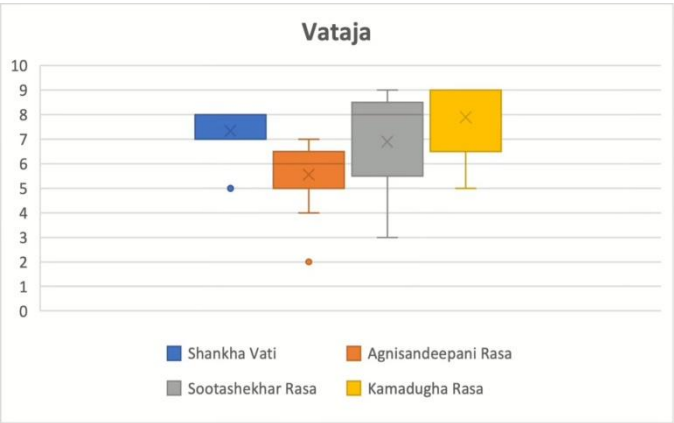

Figure 3A: Distribution of 2nd Round RAND/UCLA Panel Ratings for *Vataja Dosha* Presentation

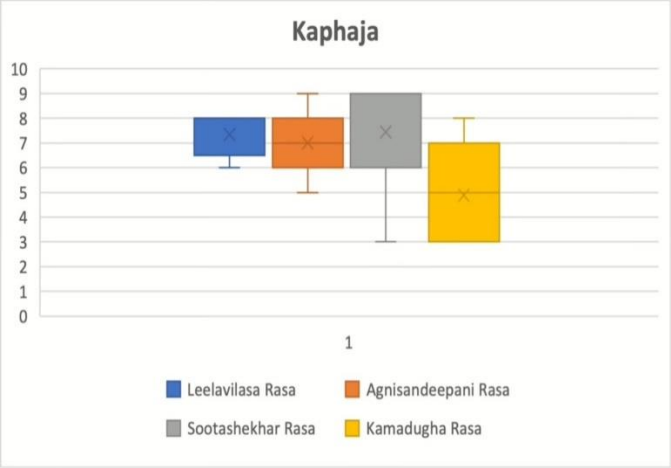

Figure 3B: Distribution of 2nd Round RAND/UCLA Panel Ratings for *Kaphaja Dosha* Presentation

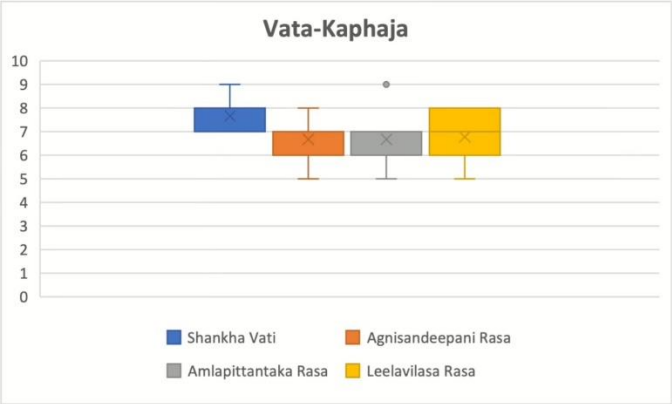

Figure 3C. Distribution of 2nd Round RAND/UCLA Panel Ratings for *Vata-Kaphaja Dosha* Presentation

Statistical Note on Agreement Assessment: RAND/UCLA method assessed agreement through inter-percentile range (IPR), defined as difference between 70th and 30th percentiles. To account for asymmetry in ratings, the disagreement index (DI) is calculated by dividing IPR by inter percentile range adjusted for symmetry. A DI value greater than 1 indicates significant disagreement, while in the current study, formulations classified as appropriate demonstrated low IPR values and DI values were well below threshold, indicating strong consensus among panelists.

3. RESULTS

Overview of the Rating Exercise: 6 unique formulations were evaluated, appearing 12 times across *dosha*-based presentations because of repetition in *Vataja* (figure 3A), *Kaphaja* (figure 3B), and *Vatakaphaja* (figure 3C) presentations of *Amlapitta*. All panel members completed both rounds of independent rating, and thus, a complete data set was available for statistical analysis. Median scores and measures of dispersion and disagreement indices were also calculated for each formulation following the second round of

ratings and were used in arriving at the final appropriateness classification. All 12 statements were rated in both rounds with full participation from all of 9 panelists. (Figure 4)

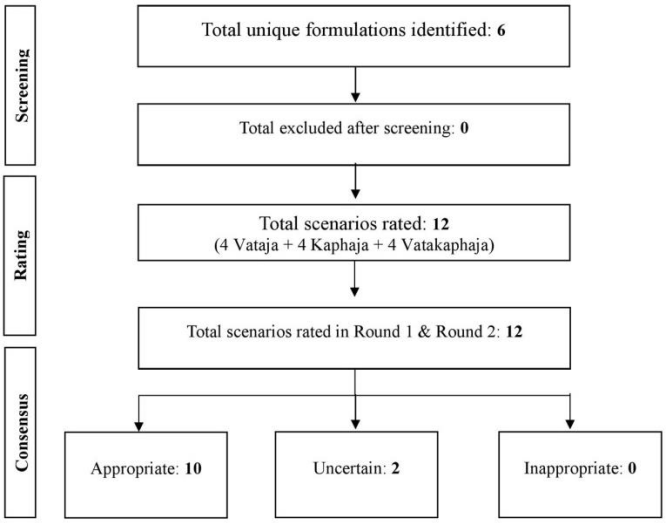

Figure 4: PRISMA–RAM Hybrid Flow Diagram of the Consensus Development Process

Overall, the distribution of ratings supported the distinction of formulations into those appropriate, uncertain, or inappropriate for particular *doshic* presentation. Formulations found to be appropriate showed high median scores (≥7), small inter-percentile ranges, and disagreement index well below the cut-off of 1, suggesting strong agreement among the panel. While formulations identified as uncertain showed mid-range median scores or wider dispersion, these formulations classified under the uncertain category were not excluded due to inefficacy but due to variability in expert judgment. Even though more than 1 formulation met criteria for appropriateness within certain *doshic* presentations, only formulation with the highest median score and strongest consensus per *dosha* category was selected during final recommendation process.

Result *Vataja Amlapitta* [15]: Among formulations incorporated for *Vataja Amlapitta, Kamadugha Rasa* obtained the highest median score of 9 with a low inter-percentile range and a disagreement index value of only 0.22 (figure 3A and Table 4), indicating strong consensus on its appropriateness. Panelists consistently reiterated formulation's classical indication in *Pitta* predominant conditions with associated *Vata* and its good tolerability profile when used in standard doses. *Shankha Vati* was also rated highly appropriate for *Vataja Amlapitta* with a median of 8 and strong agreement, consistent with its broad utility in digestive disorders with involvement of *Vata,* but failed to overcome *Kamadughda Rasa.* Although *Agnisandeepani Rasa* is classically indicated in digestive impairment, it garnered an intermediate median of 6 (Figure 3A). Even though disagreement indices were below threshold range, dispersion of ratings reflected differing views among panelists on its appropriateness in *Vataja Amlapitta,* and particularly on whether symptoms or the constitutional status of the patient should guide its usage. Grounded on these findings, it was classified as uncertain.

Results for *Kaphaja Amlapitta* [16]: In the case of *Kaphaja Amlapitta, Leelavilasa Rasa* was considered the most appropriate formulation with a median of 8, low dispersion, moderate disagreement index of 0.33 (Figure 3B and Table 4). Panelists reiterated its traditional indication in *Kapha*-associated disorders of the digestive system and perceived suitability of its overall effects in managing heaviness, nausea, and postprandial discomfort. While *Sootasekhara Rasa* had a median score within the appropriate range, greater variability of scores and a high inter-percentile range meant that appropriateness of this intervention was classified as being uncertain under our criteria. Differences in opinion among the expert panel appear to have been due to differing clinical experience of its use in *Kapha* dominant presentations and or more mixed *doshic* patterns.

Results for *Vatakaphaja Amlapitta* [17]: For *Vatakaphaja Amlapitta*, *Shankha Vati* received a median score of 8 and a strong degree of agreement among panelists (Figure 3C and Table 4), which reflects a broad consensus with respect to its suitability for a mixed *doshic* presentation. Panelists

emphasized versatility and classical use for complex digestive states associated with both *Vata* and *Kapha* derangement. *Amlapittantaka Rasa* got an intermediate median score and was classified as uncertain, as there was variable agreement among experts regarding its appropriateness. While some panelists understood that it would be beneficial, others were concerned about issues such as formulation complexity and patient selection, leading to greater dispersion in scores.

Table 4: Final Ayurvedic Formulations Selected Using the RAND/UCLA Appropriateness Method

Dosha-base Presentation of *Amlapitta*	Final Selected Formulation	Median Score	Agreement Status	Rationale for Selection
Vataja Amlapitta	*Kamadugha Rasa* [15]	9	Strong agreement (DI < 1)	Consistently high appropriateness ratings; classical indication for Pitta-dominant conditions with Vata association; low rating dispersion among experts
Kaphaja Amlapitta	*Leelavilasa Rasa* [16]	8	Strong agreement (DI < 1)	High median score with minimal dispersion; classical use in Kapha-associated digestive disorders; broad expert consensus
Vatakaphaja Amlapitta	*Shankha Vati* [17]	8	Strong agreement (DI < 1)	Demonstrated suitability for mixed doshic presentations; consistent ratings reflecting versatility in complex digestive conditions

Interpretation of Agreement and Uncertainty: The key finding that several formulations assess an indication as uncertain signifies an important feature of the RAND/UCLA approach, which does not force agreement and rather explicitly records domains of significant divergence of expert opinion, which may reflect true clinical uncertainty or context-specific uncertainty. These results further illustrate the utility of the RAND approach in documenting consensus and uncertainty, which may help or guide further research into evidence generation going ahead. It is important to emphasize that classifications of "appropriate" reflect structured expert consensus regarding clinical suitability within defined scenarios and should not be taken as either evidence of comparative clinical efficacy or therapeutic superiority. The RAND/UCLA method only assesses appropriateness and not effectiveness.

4. DISCUSSION

Pathogenesis of *Amlapitta* is described in *Madhava Nidana*. [4] On consumption of *Viruddha ahara* (incompatible food), *Pitta* vitiating *ahara*, *Vidagdha* (fermented), *Amla* (sour) ahara and in dormant stage of *Pitta*, there is *Agnimandya* (diminished digestive fire) resulting in *vidagdha ajirna* (indigestion). Because of this vitiated *Pitta* gains *guna* (characteristics) of *amla* and *Amlapitta* is produced. This is clinically presented as a manifestation of *avipaka* (impaired digestion), *klama* (fatigue), *utklesha* (nausea), *amlodgara* (sour belching), *gaurava* (heaviness), *hrit-kantha daha* (burning sensation in chest and throat) and *aruchi* (loss of appetite). Based upon associated *dosha* in pathogenesis, disease is of 3 types. *Vataja Amlapitta, Kaphaja Amlapitta* and *Vatakaphaja Amlapitta* are elaborated in classics. Summary of probable *Samprapti* outlined in figure 5. Line of treatment in *Amlapitta* adopts strategies to break *Samprapti*. This involves expulsion of *doshas* and *Pitta shamana*. *Shodhana* (purification) and *Shamana* (palliative) approach have been described in classics depending on the pathogenesis. It is further emphasized by *Yoga Ratnakara* that treatment should be based on associated *dosha* involvement. Therapeutic alternatives include *Deepana* (appetite stimulant) and *Pachana* (digestive) for correcting impaired *Agni* and *Tikta pradhana oushadhas* (bitter predominant medicines) for *Pitta shamana*. *Ahara* and *Bheshaja Kalpana* (medicine based) are tailored according to *dosha* combination. Thus line of treatment in *Amlapitta* consists of correction of *Agni, Pitta-*

shamana, expulsion of vitiated *doshas* when indicated and *dosha pratyaneeka upakrama* (therapy antagonistic to the aggravated *dosha*).

Current study adhered to core principals and components of RAND/UCLA Appropriateness Method [8-9], including independent rating, 2 round consensuses (Figure 2) and classification based on median scores and disagreement index (Table 3). However, unlike conventional biomedical applications which evaluate procedural or intervention appropriateness based primarily on clinical trial data, this study incorporated classical *Ayurvedic* textual evidence alongside contemporary biomedical literature. Apart from this, appropriateness was assessed within *dosha*-specific (Figure 3A, 3B, 3C and Table 2-4) clinical scenarios rather than standardized biomedical case definitions. These contextual adaptations were necessary to align with that of RAND framework with *Ayurvedic* epistemology while maintaining methodological rigor. To date, no studies in Ayurveda carried out based on the RAND method in order to operationalized drug selection framework model, which highlights the methodological contribution of the current study to *Ayurveda* science. It fills an important lacuna in Ayurvedic and integrative medicine research, where multiple therapeutically valid options exist but transparent, reproducible processes for intervention selection are rarely documented. A structured comparison with classical RAND studies is outlined in table 5.

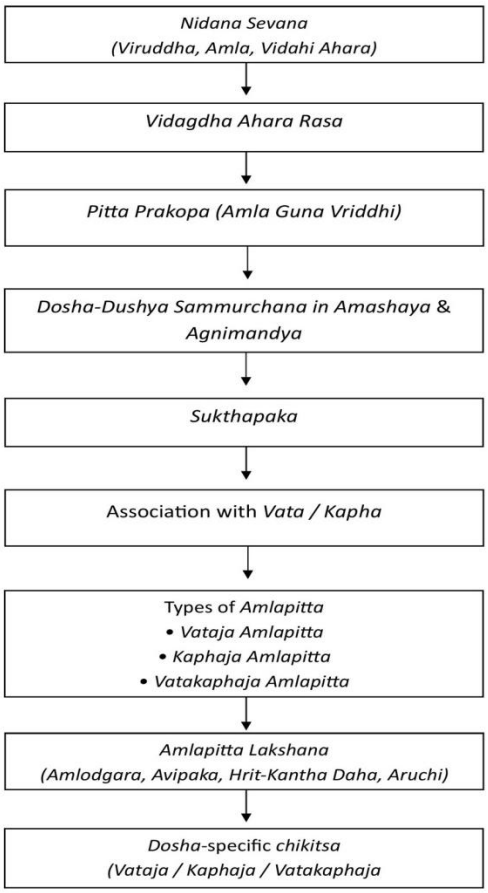

Figure 5: Probable *samprapti* of *Amlapitta*

Table 5: A structured comparison of the current study with classical RAND studies…

Methodological Component	**Classical RAND Studies**	**Present Study**	**Adaptation for *Ayurveda***
Panel Size	7–15 experts	9 experts	Multidisciplinary *Ayurveda* experts
Rating Scale	9-point appropriateness scale	9-point scale	Same
Rounds	2 rounds	2 rounds	Same
Evidence Base	Clinical trials + guidelines	Classical texts + biomedical literature	Textual + modern evidence integration
Agreement Metric	Median + DI	Median + DI	Same
Objective	Procedure appropriateness	Formulation appropriateness	*Dosha*-based drug selection

A key contribution of this work is systematic operationalizing therapeutic plurality in a structured decision-making framework. Classical Ayurvedic texts are deliberate in their description of several formulations for a single disease entity, in order to enable individualized and context-sensitive treatment. Although if this plurality is translated into clinical research outside this context without clearly stating a justification, it can lead to arbitrariness and compromise

reproducibility. The RAND/UCLA method enables this plurality to be surfaced, discussed, and documented transparently, without Ayurveda epistemology being rendered nil by it.

Explicit recognition of the distinction between appropriateness and efficacy is a major methodological advantage of the current approach. Appropriateness identifies interventions that are clinically suitable in well-defined circumstances on the basis of expectations concerning both benefits and potential risks. It is different from comparing which formulation is effective and what is not, i.e., efficacy. By viewing the question of appropriateness rather than efficacy, the current study avoids making unsubstantiated claims of treatment efficacy while still identifying a more rational as well as ethically sound basis for selecting a formulation. This distinction is particularly pertinent in the context of *Ayurveda*, where individualized clinical decision-making is so central in practice and comparative clinical trials are limited.

The advantages of the RAND/UCLA approach are apparent in comparison with alternative approaches to formulating consensus. Informal expert discussion, a common method for traditional medicine research, is prone to dominance bias and lacks methodological transparency. Delphi methods provide anonymity and iterative feedback but are optimized to achieve convergence, smoothing over rather than capturing persistent and meaningful disagreement. By comparison, RAND/UCLA approach explicitly measures and reports disagreement, recognizing disagreement as an informative outcome rather than a failure of method. In the current study, a number of formulations were classified as uncertain. This classification truly reflected divergence in expert interpretation, whether rooted in classical textual variation or clinical experience.

The relevance of this work is not restricted to the context of *Amlapitta* only. Using RAND-based selection frameworks can aid in harmonization of research practices in *Ayurveda* science, improve comparability between studies, and thereby help communicate better with biomedical researchers, regulators, as well as ethics committees. Ensuring that documentation of the selection of a formulation for clinical trials is made explicit helps enhance methodological rigor and to facilitates better critical appraisal of future clinical trials.

External Validity Considerations: Generalizability of current findings should be interpreted within the methodological framework of the Modified RAND/UCLA Appropriateness Method. Even though the panel comprised 9 experienced across multidisciplinary experts (Table 1), consensus reflects and is based purely on expert judgment within a structured framework (Figure 1-2) and not on the empirical comparative effectiveness data. Formulations evaluated were derived from classical *Ayurvedic* sources as well as contemporary clinical practice patterns, though regional prescribing traditions, practitioner training backgrounds, and patient constitution variability may influence applicability across diverse clinical practice settings. Future validation through multicentric clinical studies and real-world outcome assessments is needed, which would strengthen external validity and also support broader implementation. Apart from this, consensus statements represent scenario specific appropriateness under specific *dosha* presentations and may not fully capture or understand individualized clinical nuances central to *Ayurveda* practice.

Methodologically, major strengths of the current study include systematic evidence synthesis (Figure 1 and Figure 5), composition of a multidisciplinary panel (Table 1), structured panel calibration (Figure 2), anonymous independent ratings (Table 3) and statistical indices for assessing agreement and disagreement (Table 2, 4 and Figure 3A, 3B, 3C). Celebratory, these features enhance transparency, internal validity and reproducibility. Crucially, RAND method does not substitute individualized clinical judgement in routine care, rather it

provides standardized framework for research-oriented decision -making.

Strengths: This study systematically applied the RAND/UCLA Appropriateness Method to selecting *Ayurvedic* drugs, providing a transparent as well as reproducible framework for reconciling therapeutic plurality in *Amlapitta*. Integration of classical Ayurvedic evidence along with structured expert consensus, anonymous independent ratings and statistical assessment of agreement underpins methodological rigor as well as its credibility.

Limitations: These findings are purely based on expert judgement and narrative evidence synthesis rather than comparative clinical outcomes. Panel size and composition, despite alignment with RAND recommendations it may limit its general ease of applicability. Appropriateness ratings should not be equated with evidence of efficacy or its superiority. Panel judgments might be a result of regional practice patterns despite multidisciplinary representation. Despite the multidisciplinary panel being geographically limited to India which may have restricted generalizability beyond similar practice settings.

Future Directions: Findings from current study may be relevant for future guideline development in Ayurveda. Using a structured as well as transparent consensus process which can help to bring greater clarity with respect to formulation selection in *dosha*-based presentations of *Amlapitta*. These approaches may support academic institutions, professional bodies as well as regulatory authorities in order to develop more consistent treatment recommendations while remaining aligned with classical *Ayurvedic* principles. So this framework could also be explored for other clinical conditions apart from *amlapitta* as well, where standardization of therapeutic decision-making is a need. Future studies may corroborate selected formulations through controlled clinical trials as well and extend RAND-based selection frameworks for other Ayurvedic conditions. Inclusion of larger, multi-center panels and patient-centered outcomes may further ease of its applicability.

5. CONCLUSION

Present study employed RAND/UCLA Appropriateness Method to evaluate *dosha* based classical formulations for defined clinical presentations of *Amlapitta*. 6 formulations were evaluated across 3 clinical presentations with a total 12 rating statements based on *dosha*. After the second round of consensus, among these 10 formulations rated as appropriate (median ≥7 without disagreement), among them 3 with highest median scores were *Kamadugha Rasa* for *Vataja Amlapitta*, *Leelavilasa Rasa* for *Kaphaja Amlapitta* and *Shankha Vati* for *Vatakaphaja Amlapitta*. While other formulations were rated as uncertain. Study demonstrates that structured expert consensus can aid organization of classical knowledge and empirical clinical experience to guide *dosha* based formulation selection in defined clinical contexts. Because this was a single disease consensus study, care should be taken in interpreting the results and these findings require validation in clinical research.

Abbreviations

AJIC – American Journal of Infection Control

CI – Confidence Interval

CTRI – Clinical Trials Registry of India

DI – Disagreement Index

FD – Functional Dyspepsia

IEC – Institutional Ethics Committee

IPR – Interpercentile Range

IPRAS – Interpercentile Range Adjusted for Symmetry

PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RAM – RAND/UCLA Appropriateness Method

RCT – Randomized Controlled Trial

SD – Standard Deviation

WHO – World Health Organization

Trial registration: CTRI/2025/12/099579 (All items from the WHO Trial Registration Data Set are available in the CTRI record CTRI/2025/12/099579

Acknowledgment: Authors acknowledge support of the Institutional Ethics Committee of KAHER's Shri B.M.K. *Ayurveda* Hospital for ethical review as well as guidance. The authors also thank the faculty members and clinical staff from the Department of *Kayachikitsa* for their assistance in planning the study. Also authors sincerely thank the expert panelists involved for their valuable contributions to the selection and validation of the Ayurveda treatment protocol using the RAND/UCLA Appropriateness Method.

Authors Details:

[1]Post Graduate Scholar, Department of Kayachikitsa, KLE Academy of Higher Education and Research, Deemed to be University, Shri BMK Ayurveda Mahavidyalaya, Shahpur, Belagavi, Karnataka, India-590003

[2*]Associate Professor, Department of Kayachikitsa, KLE Academy of Higher Education and Research, Deemed to be University, Shri BMK Ayurveda Mahavidyalaya, Shahpur, Belagavi, Karnataka, India-590003

[3]Associate Professor, Department of Manasaroga, KLE Academy of Higher Education and Research, Deemed to be University, Shri BMK Ayurveda Mahavidyalaya, Shahpur, Belagavi, Karnataka, India-590003

[4]Post Graduate Scholar, Department of Kayachikitsa, KLE Academy of Higher Education and Research, Deemed to be University, Shri BMK Ayurveda Mahavidyalaya, Shahpur, Belagavi, Karnataka, India-590003

Authors Contribution:

Conceptualization and Clinical Management: VZ, R.SD

Data Collection and literature search: VZ, BP, RBS

Writing -Original Draft: VZ, BP

Proofreading/Copyediting: RBS, BP, R.SD

Consent to Publish Final Manuscript: All authors

Declaration of Generative AI

The authors declare this manuscript was written without the use of generative artificial intelligence tools. All the content, including text generation, data analysis and references was developed and reviewed by the author without assistance from AI technologies.

Conflict of Interest – The authors declare no conflicts of interest.

Source of Support – The authors declare no source of support.

Additional Information:

Authors can order reprints (print copies) of their articles by visiting: **https://www.akinik.com/products/2281/journal-of-ayurveda-and-holistic-medicine-jahm**

Publisher's Note:

Atreya Ayurveda Publications remains neutral with regard to jurisdictional claims in published maps, institutional affiliations, and territorial designations. The publisher does not take any position concerning legal status of countries, territories, or borders shown on maps or mentioned in institutional affiliations.

REFERENCES:

1. Shankar H. Clinical prevalence and current treatment standards for GERD and dyspepsia, and perception of effectiveness and safety of itopride in Indian patients: a physician survey. *Journal of Advanced Scientific Research.*2023;14:25–34. Available from: https://www.sciensage.info/jasr/?page_id=4070
2. Francis P, Zavala SR. Functional dyspepsia. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan– [updated 2024 Jun 8]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK554563/
3. Yadav B, Mahajan B, Dubey N, Panda AK, Rao BC, Singhal R, et al. Traditional Ayurveda medicines for the management of Amlapitta (functional dyspepsia): a study protocol for a prospective, single-arm, open-label clinical trial. *Journal of Ayurveda and Integrative Medicine.* 2023;14(4):100654. Available from: https://doi.org/10.1016/j.jaim.2023.100654
4. Sastri S, editor. *Vidyotini Hindi Commentary on Madhava Nidana of Madhavakara.* Amlapitta Nidana, chapter 51, verse no.7–10. Varanasi: Chaukhambha Prakashan; 2010;172.
5. Tripathi B, editor. *Charaka Samhita of Agnivesha with Charaka Chandrika Hindi Commentary.* Chikitsasthana, Grahani Chikitsa Adhyaya, chapter 15, verse no.47. Varanasi: Chaukhambha Surbharati Prakashan; 2019;559.
6. Ashwathykutty V, Payyappallimana U, Narayanan VR. Addressing clinical practice variability in Ayurveda: An urgent need for developing clinical practice guidelines. *Journal of Ayurveda and Integrative Medicine.* 2025 Sep–Oct;16(5):101201. Available from: https://doi.org/10.1016/j.jaim.2025.101201
7. World Health Organization. WHO global report on traditional and complementary medicine 2019. Geneva: World Health

Organization; 2019. ISBN: 9789241515436. Available from: https://iris.who.int/handle/10665/312342

8. World Health Organization. WHO traditional medicine strategy 2014–2023. Geneva: World Health Organization; 2013. Available from: https://iris.who.int/bitstream/10665/92455/1/9789241506090_eng.pdf
9. Ministry of AYUSH. *Ayurvedic Standard Treatment Guidelines*. 1st ed. Ministry of AYUSH, Government of India; 2017. Available from: https://namayush.gov.in/sites/all/themes/webcms/images/org_str/ASTG_Book.pdf. Accessed on 13 February 2026.
10. Chauhan A, Semwal DK, Mishra SP, Semwal RB. Ayurvedic research and methodology: Present status and future strategies. *Ayu.* 2015;36(4):364–369. doi:10.4103/0974-8520.190699. Available from: https://pubmed.ncbi.nlm.nih.gov/27833362/
11. RAND Corporation. Appropriateness Method. Available from: https://www.rand.org/health/surveys/appropriateness.html. Accessed on December 30, 2025.
12. Campbell JL, Fletcher E, Abel G, et al. Workstream 4: The RAND/UCLA Appropriateness Method. In: *Policies and strategies to retain and support the return of experienced GPs in direct patient care: the ReGROUP mixed-methods study.* NIHR Journals Library; 2019. Available from: https://www.ncbi.nlm.nih.gov/books/NBK539926/. Accessed on December 30, 2025.
13. Fitch K, Bernstein SJ, Aguilar MD, et al. *The RAND/UCLA Appropriateness Method User's Manual.* RAND Corporation; 2001. Report No.: MR-1269. Available from: https://www.rand.org/content/dam/rand/pubs/monograph_reports/2011/MR1269.pdf. Accessed on December 30, 2025.
14. Charles KR, Hall L, Ullman AJ, Schults JA. Methodology minute: Utilizing the RAND/UCLA appropriateness method to develop guidelines for infection prevention. *American Journal of Infection Control.* 2022;50(3):345–348. Available from: https://doi.org/10.1016/j.ajic.2021.12.012
15. Mishra SN, editor. *Bhaishajya Ratnavali of Govind Das Sen with Siddhiprada Hindi Commentary.* Amlapitta Rogadhikara, chapter 56, verse no.25–29. Varanasi: Chaukhambha Surbharati Prakashan; 2005;922.
16. Acharya YT, editor. *Rasa Yoga Sagara.* 2nd edition. Varanasi: Chaukhambha Sanskrit Sansthan; 2004. Kamadugha Vati;103.
17. Sharma S, editor. *Rasa Tarangini.* 11th edition. Delhi: Motilal Banarsidass; 2017. Chapter 22, Shankha Vati Yoga;498.
18. Nair D, Gaonkar S, Lakshmi KNC. Utility of Rasadravyas in Panchakarma. *Journal of Ayurveda and Holistic Medicine (JAHM).* 2019;7(2):66. Available from: https://jahm.co.in/index.php/jahm/article/download/62/36/152. Accessed on January 4, 2026.