



A Clinical Evaluation Of Amaladya Lauha In Management Of Urdhwag Amlapitta

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ABSTRACT

Amlapitta is a frequently observed disorder of the *Annavaha Srotas* described in classical Ayurvedic literature, arising primarily due to derangement of *Agni* and vitiation of *Pitta Dosha*. Clinically, it presents with symptoms such as *Avipaka* (indigestion), *Hritkantha Daha* (burning sensation in the chest and throat), and *Tikta-Amlodgara* (sour-bitter belching), which closely resemble gastroesophageal reflux disease. *Amaladya Lauha*, a classical herbo-mineral formulation mentioned in *Rasendrasar Sangraha*, is traditionally indicated in the management of *Amlapitta*.

A randomized control clinical study was carried out on 72 patients diagnosed with classical features of *Amlapitta*. The patients were randomly divided into two groups. The trial group was administered *Amaladya Lauha* in a dose of 250 mg twice daily after meals for 14 days, while the control group received capsule Omeprazole 20 mg once daily before lunch for the same duration. Assessment of therapeutic response was based on subjective clinical parameters including *Tikta-Amlodgara*, *Avipaka*, *Utklesha*, *Klama*, *Gauravata*, *Hritkantha Daha*, and *Aruchi*. Statistical analysis was performed using the Wilcoxon signed-rank test for intra-group comparison and the Mann-Whitney U test for inter-group comparison.

The results revealed that both *Amaladya Lauha* and Omeprazole produced statistically significant improvement in the clinical features of *Urdhwag Amlapitta*. Comparative statistical analysis showed no significant difference between the two groups.

The study concludes that *Amaladya Lauha* is therapeutically comparable to Omeprazole in the management of *Urdhwag Amlapitta* and may serve as an effective Ayurvedic intervention in its treatment.

KEYWORDS: *Amlapitta, Annavaha Strotas, Amaladya Lauha, Omeprazole, GERD.*

INTRODUCTION

Ayurveda, one of the world's oldest health sciences, emphasizes the balance of *Dosha, Dhatu*, and *Mala* as the foundation of well-being.^[1] The *Tridosha—Vata, Pitta* and *Kapha*—governs both physical and mental functions, and their imbalance leads to various disorders.^[2,3] Dietary irregularities and lifestyle changes disturb the *Annavaha Strotas*, resulting in digestive conditions, among which *Amlapitta* is common. It occurs due to the vitiation of *Pitta*, especially its *Amla Guna*.^[4]

Although *Amlapitta* is not directly mentioned in the *Brihatrayi*, it is described in detail in *Kashyapa Samhita, Madhava Nidana, Bhavaprakasha* and *Yoga Ratnakara*. *Charaka* explains its pathogenesis under *Grahani Roga*, where impaired *Agni* leads to *Amla Anna-Visha* formation, causing symptoms of *Amlapitta*.^[5] *Madhava Nidana* states that excessive *Pitta*-provoking factors increase *Amla Guna*, producing *Amlapitta*.^[6]

Amlapitta is classified as *Vataj, Pittaj* and *Kaphaj* by *Kashyapa*, and into *Urdhwag* and *Adhog* types by *Madhava Nidana*. *Urdhwag Amlapitta* presents with *Tiktamlodgara, Avipaka, Utklesha, Klama, Gauravta, Hritkantha Daha*, and *Aruchi*.^[7] It closely correlates with Gastroesophageal Reflux Disease (GERD), which affects around 15.6% of the Indian population.^[8,9] Modern management includes antacids, H2 blockers, and proton pump inhibitors, but long-term use may cause adverse effects such as vitamin B12 deficiency, nausea, diarrhea and constipation.^[10]

With rising digestive disorders due to lifestyle changes, safe and effective herbal alternatives are needed. *Amaladya Lauha*, mentioned in *Rasendrasar Sangraha*, is traditionally indicated for *Amlapitta*.^[11] Being affordable and potentially suitable for routine use, it warrants scientific evaluation. Therefore, this study aims to assess the efficacy of *Amaladya Lauha* in the management of *Urdhwag Amlapitta*.

AIM

To evaluate efficacy of *Amaladya Lauha* in *Urdhwag Amlapitta*.

OBJECTIVES

To compare efficacy of *Amaladya Lauha* and *Omeprazole* in *Urdhwag Amlapitta*.

MATERIALS AND METHODS

Study Design and Participants

A total of 72 patients presenting with classical symptoms of *Amlapitta* and attending the OPD of the Kayachikitsa Department, Dhanwantari Hospital, Ashta, Sangli, Maharashtra were enrolled irrespective of gender, occupation or religion. Patients were selected according to pre-defined inclusion and exclusion criteria. The study commenced after approval from the Institutional Ethics Committee (IEC/SVAYC/RS/15/49, dated 26-03-2015) and CTRI registration (CTRI/2025/03/082879). Written informed consent was obtained from all participants.

Inclusion Criteria

- Patients aged 18–60 years.
- Individuals of any gender, occupation, and marital status.
- Patients presenting with symptoms of *Urdhwag Amlapitta* (*Tiktamlodgara*, *Avipaka*, *Utklesha*, *Klama*, *Gauravta*, *Hritkanthadaha*, *Aruchi*) with history < 1 year.

Exclusion Criteria

- Patients with chronic conditions such as Gastric or Peptic ulcer, Diabetes, Colon cancer, IBS, Celiac disease or Autoimmune disorders.
- Regular NSAID users.
- Patients with bleeding disorders.
- Pregnant or lactating women.

Withdrawal Criteria

- Discontinuation or unwillingness to continue treatment.
- Failure to attend follow-up visits.
- Emergence of new complaints, serious complications, or ADRs.

Intervention and Grouping

Table no – 1 Intervention and Grouping

Parameter	Group A	Group B
No. of subjects	36	36
Drug	<i>Amaladya Lauha</i>	Capsule Omeprazole
Duration	14 days	14 days
Dose	250 mg twice daily	20 mg once daily
Route	Oral	Oral
Timing	After food (morning/afternoon and night)	Before food (morning/afternoon)
Anupan	Warm water	Water
Follow-up	Day 7 and Day 14	Day 7 and Day 14

Preparation of *Amaladya Lauha*

Ingredients and properties of *Amaladya Lauha*

आमलापिप्पलीचूर्ण तुल्यया सितया सह । रक्तपित्तहरम् लौहम् योगराजमिदम् स्मृतम् ॥

वृष्याअग्निदिपनम् बल्यमम्लपित्तिनाशनम् । पित्तोत्थानपि वातोत्थान् निहन्ति विविधान् गदान् ॥

(रसेन्द्रसारसन्ग्रह 3/4)^[11]

Table no – 2 Ingredients and properties of Amaladya Lauha

SR NO	DRUG NAME	LATIN NAME	GUNA	RASA	VIRYA	VIPAKA	DOSHA GHANATA	PHARMACOLOGICAL ACTIONS
1	Amalaki ^[12]	<i>Emblica officinalis</i>	<i>Guru, Ruksha, Sheeta</i>	<i>Amla</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Kapha -Pitta Shamak</i>	Antioxidant, Anti-inflammatory, Immune-modulating, Liver protector ^[16]
2	Pippali ^[13]	<i>Piper longum</i>	<i>Laghu, Snigdha</i>	<i>Katu</i>	<i>Anushna Sheeta</i>	<i>Madhura</i>	<i>Pittashamak</i>	Antioxidant, Anti-inflammatory, Memory enhancement, Liver protector ^[17]
3	Sita ^[14]	<i>Saccarum officinarum</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Vata- Pitta Shamak</i>	Antioxidant Properties, Blood Pressure Management, Aphrodisiac and Tonic ^[14]
4	Lauha Bhasma ^[15]	<i>Ferrum</i>	<i>Sara, Guru, Ruksha</i>	<i>Tikta, Madhura, Kashaya</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Tridoshanashak</i>	Anti-anaemic, Anti-bacterial, Anti-inflammatory, Antioxidant, Aphrodisiac, Anti-Ageing, Analgesic, Antipyretic ^[18]

Raw Material Collection and Authentication

Amalaki, Pippali, Sita and *Lauha Bhasma* were procured from the local market. Identification was carried out in the Department of Dravyaguna and authentication was done at a certified analytical laboratory.

Procedure

One part each of *Amalaki, Pippali,* and *Sita,* and three parts of *Lauha Bhasma* were mixed thoroughly. Tablets of 250 mg were prepared in a GMP-certified pharmacy as per *Rasendra sar Sangraha*.

Assessment Criteria

General Observations

Demographic variables such as age, occupation, marital status and religion were documented.

Subjective Parameters

Symptoms of *Urdhwag Amlapitta* were scored using a grading system before treatment and on day 7 and day 14.

Assessed symptoms:

1. *Tiktamlodgara*
2. *Avipaka*
3. *Utklesha*
4. *Klama*
5. *Gauravta*
6. *Hritkanthadaha*
7. *Aruchi*

Symptom Grading Scale

Table no – 3 Symptom Grading Scale

Symptom	Grade 0	Grade 1	Grade 2	Grade 3
<i>Tiktamlodgara</i>	No Belching	Feeling of belching with no sound	Feeling of belching with mild sound	Feeling of belching with severe sound
<i>Avipaka</i>	No Indigestion	Unable to digest mild fatty food.	Unable to digest 3-course meal	Unable to digest any kind of food.
<i>Utklesha</i>	No nausea	Mild nausea	Severe nausea	Severe nausea with vomiting
<i>Klama</i>	No tiredness	Feel tired after exertional work	Feel tired after normal work	Feel tired even after taking rest
<i>Gauravta</i>	Normal	Feeling of heaviness in morning	Feeling of heaviness in morning & evening after food	Feeling of heaviness always
<i>Hritkanthadaha</i>	No burning sensation	Sensation of warmth on throat occasionally	Burning sensation of throat and chest after mild oily / spicy food	Feeling of burning sensation continues
<i>Aruchi</i>	No Aruchi	Patient feels Aruchi but takes food time to time	Patient Sometimes takes food and Sometimes Avoid it	Patient Avoid the food many times

Table no – 4 Overall Assessment of Therapy

Class	Improvement (%)
Complete improvement	76–100%
Marked improvement	51–75%
Mild improvement	26–50%
No improvement	<25%

Statistical Analysis

Data were analysed using Wilcoxon Signed-Rank Test for intragroup comparison and Mann–Whitney U Test for intergroup comparison. Results were interpreted as:

$P > 0.05$: Not significant $P < 0.05$: Significant

OBSERVATIONS

A total of 76 patients with signs and symptoms of *Urdhwag Amlapitta* were registered. Out of them, 72 patients completed the course of treatment. Four patients dropped out due to unknown reasons.

In the present study, a total of 72 patients were enrolled, equally divided into two groups of 36 each. Maximum patients belonged to the 18–30 years age group (47.22%), followed by 31–40 years (15.27%), while only a few were from 41–50 years (8.33%) and 51–60 years (1.38%).

A male predominance was observed, with 49 (68%) males and 23 (32%) females. The majority of patients were Hindu (75%), followed by Buddhists (21%) and Muslims (4%).

Students formed the largest occupational group (30.55%), followed by jobholders (27.77%), housewives (15.27%), farmers (11.11%), teachers (8.33%) and business persons (6.94%).

Most patients belonged to the middle class (37.50%), while 30.55% were from upper-middle and 31.95% from lower-middle socioeconomic groups.

With respect to *Prakruti*, *Vata-Pitta* was most common (38.88%), followed by *Vata-Kapha* (16.66%), *Kapha-Pitta* (12.05%), *Pitta-Vata* (11.11%), *Pitta-Kapha* (5.55%) and *Kapha-Vata* (5.55%).

Tikshna Agni was present in the majority (55.55%), followed by *Vishama Agni* (34.72%), while only 9.72% had *Manda Agni*.

Most patients exhibited *Madhyam Koshtha* (72.22%), whereas *Mrudu Koshtha* was seen in 25% and *Krura Koshtha* in only 2.77%.

A high proportion of patients had *Asamyaka Nidra* (86.11%), reflecting disturbed sleep patterns. Regarding diet, 68% consumed a mixed diet, while 32% were vegetarians.

Table no – 5 Effect of Therapy on subjective parameters in 72 patients

Symptoms	Group	Mean BT	Mean AT	Mean Diff.	Z-Value	P-Value	% Relief	U Value	P (MW Test)	Interpretation
Tiktamlodgara	A	1.917	0.611	1.306	-5.23	<0.05	68.12%	642.5	0.95	No significant difference
	B	1.917	0.583	1.333	-5.23	<0.05	69.57%			
Avipaka	A	1.722	0.639	1.083	-5.01	<0.05	62.90%	552.5	0.27	No significant difference
	B	1.722	0.472	1.25	-5.08	<0.05	72.58%			
Utklesha	A	1.667	0.556	1.111	-5.01	<0.05	66.67%	617	0.72	No significant difference
	B	1.667	0.500	1.167	-5.08	<0.05	70%			
Klama	A	1.639	0.527	1.111	-5.08	<0.05	67.80%	648	0.99	No significant difference
	B	1.639	0.527	1.111	-5.08	<0.05	67.80%			
Gauravta	A	0.750	0.250	0.50	-3.18	<0.05	66.67%	633	0.86	No significant difference
	B	0.778	0.250	0.527	-3.17	<0.05	66.86%			
Hritkanthadaha	A	1.806	0.667	1.139	-4.72	<0.05	63.08%	619	0.74	No significant difference
	B	1.806	0.611	1.194	-4.70	<0.05	66.15%			
Aruchi	A	0.861	0.250	0.611	-3.81	<0.05	70.97%	553	0.28	No significant difference
	B	1.222	0.445	0.778	-4.10	<0.05	63.64%			

(n: Number of patients suffering from symptoms, BT: Arithmetic mean of scoring before treatment, AT: Arithmetic mean of scoring after treatment, SD: Standard deviation, SE: Standard error, P: Significance of treatment on specific symptoms)

• Both groups showed statistically significant improvement ($P < 0.05$) in all major symptoms of *Urdhwag Amlapitta*, including *Tiktamlodgara*, *Avipaka*, *Utklesha*, *Klama*, *Gauravta*, *Hritkanthadaha* and *Aruchi*, as reflected by the intragroup Wilcoxon Signed-Rank Test. The percentage relief in symptoms ranged approximately from 62% to 71% in both groups. However, the intergroup comparison using the Mann–Whitney U Test revealed no significant difference between Group A and Group B across all symptoms ($P > 0.05$), indicating that both interventions were equally effective in reducing the clinical features of *Urdhwag Amlapitta*.

Table no – 6 Overall effect of therapy according to subjective criteria on 72 patients of *Urdhwag Amlapitta*

Result	Group A		Group B	
	Number of patients	%	Number of patients	%
Complete improvement (76 - 100 %)	10	27.78%	12	33.33%
Markedly improvement (51 – 75 %)	24	66.67%	24	66.67%
Mild improvement (26 – 50 %)	2	5.56%	0	0.00%
No improvement (0 to 25 %)	0	0.00%	0	0.00%

Assessment of overall therapeutic response showed that complete improvement was observed in 27.78% of patients in Group A and 33.33% in Group B. Marked improvement was the most common outcome in both groups, seen in 66.67% of patients. Mild improvement was reported in 5.56% of Group A patients, while none in Group B showed only mild improvement. Importantly, no patient in either group remained unimproved, indicating that both treatments were highly effective.

DISCUSSION

In this study, 72 patients of *Urdhwag Amlapitta* were equally divided into two groups (36 each). The highest incidence was seen in the 18–30 years age group (47.22%), followed by 31–40 years (15.27%), showing that younger adults are more affected due to lifestyle and dietary irregularities. Males formed 68% of the study population, indicating higher exposure to stress and erratic food habits. Hindus constituted 75% of patients due to regional demographics.

Students represented the largest occupational group (30.55%), followed by jobholders (27.77%), suggesting that mental stress and irregular routines significantly contribute to *Amlapitta*. Socioeconomically, 37.50% belonged to the middle class. Most patients had *Vata-Pitta Prakruti* (38.88%), supporting the role of *Pitta* dominance in disease manifestation. *Tikshna Agni* was observed in 55.55%, *Vishama Agni* in 34.72% and *Manda Agni* in 9.72% of cases, indicating that increased and irregular digestion are major factors. *Madhyam Koshtha* (72.22%) was most common, and *Asamyaka Nidra* (86.11%) was prevalent, highlighting the role of disturbed sleep. A mixed diet was consumed by 68% of patients.

Urdhwag Amlapitta occurs when vitiated *Pitta* moves upward due to *Agnimandya*, producing symptoms like *Tiktamlodgara*, *Hritkantha daha*, *Utklesha* and *Aruchi*. Excess intake of *Amla*, *Katu*, *Lavana*, *Viruddha ahara*, *Adhyashana*, *Divaswapa* and mental stress further aggravate *Pitta* and weaken *Agni*. *Pitta* is the main *dosha* with *Kapha* as *anubandha* and *Rasa-Rakta* are the chief *dushyas*. *Annavaha* and *Rasavaha strotas* are primarily involved.

The *samprapti* begins with *Agnimandya* → *Ama* formation → *Ama* combining with *Pitta* → *Amlapitta* → upward movement of vitiated *Pitta* leading to *Urdhwag Amlapitta*. Management focuses on *Agnideepana*, *Pachana*, *Pitta-shamana*, evacuation of vitiated *doshas* if required, and adoption of *Pathya-Apathya*. Thus, restoring *Agni* and balancing *Pitta* are central to preventing recurrence and ensuring long-term relief.

MODE OF ACTION OF AMALADYA LAUHA

Amaladya Lauha contains ingredients with *Deepana-Pachana*, *Pittashamana*, and *Ropana* properties, making it effective in *Urdhwag Amlapitta*.

Lauha Bhasma

Acts as *Agnideepana* and *Pachana*, reduces *Ama*, regulates gastric secretions, pacifies *Pitta* due to *Sheeta Veerya* and *Madhura Vipaka* and supports mucosal repair through *Ropana* action.

Amalaki

With *Sheeta Veerya*, *Madhura Vipaka* and *Rasayana* properties, it soothes gastric mucosa, reduces burning, stabilizes *Pitta* and promotes mucosal healing.

Pippali

Enhances *Agni*, improves digestion, removes *Ama*, regulates acid secretion, and supports mucosal protection through *Rasayana* action.

Sharkara (Sita)

Neutralizes acidity, pacifies *Pitta* and aids mucosal healing due to its *Sheeta Veerya* and *Madhura Rasa*.

Overall Mechanism

The combined *Deepana*, *Pachana*, *Pittashamana*, *Dahashamana* and *Ropana* actions of *Amaladya Lauha* helps to normalize *Agni*, reduces *Amla Pitta* formation, soothes the gastric mucosa and break the *Samprapti*. Thus, the formulation provides effective symptomatic relief and supports complete restoration of digestive balance in *Urdhwag Amlapitta*.

CONCLUSION

The findings of the present clinical study indicate that *Amaladya Lauha* produced notable improvement in the clinical parameters of *Urdhwag Amlapitta*. Overall, the formulation demonstrated good efficacy in managing *Urdhwag Amlapitta* and no adverse reactions were observed throughout the study period. As the trial was conducted on a relatively small sample size, further research with a larger cohort and additional clinical parameters is recommended to validate these outcomes and assess its role in preventing recurrence.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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