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Research Article

A RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF *SIMHASYADI KWATHA* AND *PATOLADIPANCHANGA KWATHA* IN MANAGEMENT OF *AMLAPITTA*

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ABSTRACT

Amlapitta is a common disorder of the *Annavaha Srotas* characterized by *Agnimandya*, *Ama* formation, and *Pitta Dushti*. Its clinical features closely resemble those of gastroesophageal reflux disease and dyspepsia. *Amlapitta* is *Tridoshaja amasyodbhava roga* with predominance of *Pitta* and *Kapha*. It also associated with *Agnimandhya* and also *Amavastha*. The drugs which possess the properties like *Tikta, Kashaya Rasa,Madhura Katu Vipaka, Pitta Shamaka*, *Agni Deepak, Ama pachaka* will help in the management of *Amlapitta*. **Aim:** To evaluate and compare the efficacy of *Simhasyadi Kwatha* and *Patoladipanchanga Kwatha* in the management of *Amlapitta*. **Materials and Methods:** A randomized comparative clinical study was conducted on 60 patients diagnosed with *Amlapitta*. Patients were randomly allocated into two groups of 30 each. **Intervention:** Group A received *Simhasyadi Kwatha* (25ml twice daily before food) with *Madhu* as *Anupana*, while Group B received *Patoladipanchanga Kwatha* (25ml twice daily before food) with *Madhu* as *Anupana* for 30 days. Clinical assessment was based on *Avipaka, Klama, Utklesa, Tikta-Amla Udgara, Gourava, Hrit-Kantha Daha*, and *Aruchi*. **Results:** Both groups showed statistically significant improvement in all assessed parameters following treatment. *Patoladipanchanga Kwatha* demonstrated relatively greater percentage relief in most symptoms, whereas *Simhasyadi Kwatha* showed better improvement in *Avipaka*. However, intergroup comparison revealed no statistically significant difference between the two groups. **Conclusion:** From the study it can be concluded that both *Simhasyadi Kwatha* and *Patoladipanchanga Kwatha* proved effective in the management of *Amlapitta* with comparable therapeutic efficacy. However, group 2 showed slightly better response.

INTRODUCTION

Digestive disorders have become increasingly common in recent years due to unhealthy dietary habits, irregular meal timings, fast-paced lifestyles, and psychological stress. Such factors adversely affect the normal functioning of the digestive system and contribute to the development of various gastrointestinal disorders. In Ayurveda, these conditions are often linked to disturbances in the *Annavaha Srotas*, among which *Amlapitta* is one of the most frequently encountered disorders in clinical practice.

Although *Amlapitta* is not described as an independent disease in the *Brihattrayi*, detailed explanations of its causes, symptoms, and management are available in classical Ayurvedic texts such as *Kashyapa Samhita*[1], *Madhava Nidana*[2], *Bhavaprakasha*[3], and *Yoga Ratnakara* [4]. According to Madhavakara, *Amlapitta* develops due to the vitiation of *Pitta Dosha* associated with impaired digestion and is characterized by symptoms such as indigestion (*Avipaka*), nausea (*Utklesha*), sour or bitter belching (*Tikta-Amlodgara*), burning sensation in the chest and

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throat (*Hrid-Kantha Daha*), loss of appetite (*Aruchi*), fatigue (*Klama*), and a feeling of heaviness (*Gourava*)[2].

The clinical presentation of Amlapitta closely resembles gastroesophageal reflux disease (GERD), one of the most common gastrointestinal disorders worldwide. A recent meta-analysis reported a pooled prevalence of GERD in the Indian population of approximately 15.6% (95% CI: 11.0–20.7%). Furthermore, the Indian Society of Gastroenterology has reported that the prevalence of GERD in India ranges from 7.6% to 30%, with most population-based studies showing a prevalence below 10% [5]. The growing prevalence of GERD and related acid-peptic disorders has increased the demand for safe, effective, and sustainable treatment options.

From an Ayurvedic perspective, *Amlapitta* originates from *Agnimandya* (diminished digestive fire), which leads to the formation of *Ama* and subsequent vitiation of *Pitta* and *Kapha Doshas*. Therefore, formulations possessing *Deepana* (appetizing), *Pachana* (digestive), and *Pittashamaka* (*Pitta*-pacifying) properties are considered useful in its management [6].

Simhasyadi Kwatha, a classical formulation described in *Chakradatta* [7], has demonstrated clinical efficacy in the management of *Amlapitta* in previous studies and was therefore chosen as the standard comparator for the present trial. *Patoladi Panchanga Kwatha* is a classical Ayurvedic formulation containing *Patola, Nimba, Amalaki, Bibhitaki,* and *Haritaki*. These ingredients are known for their ability to improve digestion, eliminate *Ama*, and alleviate aggravated *Pitta*.

Considering the therapeutic importance of these formulations and the need for comparative clinical evidence, the present randomized comparative clinical study was undertaken to evaluate and compare the efficacy of *Patoladi Panchanga Kwatha* and *Simhasyadi Kwatha* in the management of *Amlapitta*.

OBJECTIVES OF STUDY

1. To determine the efficacy of *Simhasyadi Kwatha* in the management of *Amlapitta*.
2. To determine the efficacy of *Patoladipanchanga Kwatha* in management of *Amlapitta.*
3. To compare the efficacy of *Simhasyad*i *Kwatha with Patoladipanchanga Kwatha* in management of *Amlapitta*

METHODOLOGY

Study design: Single blind randomised comparative clinical study with pre and post evaluation.

Sampling Process

Sampling population

OPD and IPD of ALNRMAMC Koppa and its Branch hospital at QH Hospital Koppa.

Sample Size

A total 60 subjects (excluding dropouts) diagnosed with *Amlapitta* were selected and randomly categorised into 2 groups consisting each of 30 subjects.

Sources of Study

Clinical Source

- Subjects diagnosed with *Amlapitta* were selected from OPD and IPD of ALNRMAMC, Koppa and associated hospitals.
- 60 participants were randomly categorized into two groups (30 each) using block randomization.
- Informed consent was obtained from all participants/guardians, and clearance was granted by the Institutional Ethical Committee.

Literary Source

- Classical Ayurvedic texts, modern reference books, scientific journals, and online databases were reviewed for theoretical background on Amlapitta.
- Relevant literature on formulation preparation, dosage, and therapeutic references was also studied.

Pharmaceutical Source

- *Simhasyadi Kwatha* and *Patoladi Panchanga Kwatha* were prepared in the ALNRMAMC pharmacy, following standard *Kashaya Kalpana* methods as per AFI guidelines.

Preparation of the Medicine

Ingredients of *Simhasyadi kwatha*[7]

S.no	Drug	Part used	Quantity
1	*Vasa*	Leaves, Roots	1 Part
2	*Guduchi*	Stem	1 Part
3	*Brihati*	Pachanga	1 Part

Ingredients of *Patoladipanchanga kwatha*[7]

S.no	Drug	Part used	Quantity
1.	*Patola*	Leaves, Roots	1 Part
2.	*Amalaki*	Stem	1 Part
3.	*Haritaki*	Dried fruit	1 Part
4.	*Bibitaki*	Dried fruit	1 Part
5.	*Nimbha*	Dried fruit	1 Part

Preparation of Study Drugs

The study drugs were prepared according to the standards specified in the Ayurvedic Formulary of India (AFI)[8]. Raw materials were procured from GMP certified Pharmacy, authenticated, dried, pulverized individually, and sieved through mesh size 80. The powdered ingredients were mixed uniformly using a cone blender and stored in airtight containers. *Kashaya Churna* was packed and labelled appropriately for clinical use.

Administration of Study Drugs

The subjects were given packets required for 15 days and advised for follow up and again 15 days' medication was given. The *Kashaya churna* packets were made by weighing 750gm per packet. For the patient's convenience each packets contained 13 smaller packets weighing 50gm, 3 packets were given to one patient. Subjects were advised to prepare fresh *Kashaya* every morning and evening by adding 50gm of *Kashaya Churna* with 400ml of warm water and made to boil till it is reduced to ¼th (100ml). Subjects were advised to take 25ml *Kashaya* twice daily before food for a period of 1 month (4 weeks).

Study Procedure

Primary data were collected through direct patient interview method using a pre-designed case record proforma. Detailed history taking, clinical examination, and assessment of subjective and objective parameters were carried out at baseline. Patients fulfilling the diagnostic and inclusion criteria for *Amlapitta* were enrolled after obtaining written informed consent.

A total of 60 eligible subjects were randomly allocated into two groups of 30 each. Group A received *Simhasyadi Kwatha,* while Group B received *Patoladi Panchanga Kwatha*. Participants were advised regarding the prescribed dosage, *Pathya-Apathya*, and follow-up schedule throughout the study period.

Diagnostic Criteria

Patient will be diagnosed based on *Pratyatmaka Lakshana's* (cardinal features) of Amlapitta mentioned in classics *Avipaka, Klama, Uthklesha, Tikta Amlodgara, Gourava, Hruthkanta daha, and Aruchi.* These *Lakshana's* will be assessed and further graded by adopting Likert scale [9]

Inclusion Criteria

1. Subject of either sex.
2. Subject within the age group 18-60 yrs.
3. Subjects with clinical features of *Amlapitta such as Avipaka, Klama, Uthklesh, Tikta Amlodgara, Gourava, Hruthkanta daha,* and *Aruchi* will be included.
4. Subjects with controlled systemic disorder such as DM, HTN, etc will be included.
5. Subjects who are willing to give written consents for the study.

Exclusion Criteria

1. Pregnant and lactating women.
2. Subjects with uncontrolled systemic disorder such as Diabetes mellitus, Hypertension, etc.
3. Subject diagnosed with Gastro- intestinal disorders like peptic ulcer, pancreatic and hepatic disorders.
4. Subjects with history of haematemesis, malena and other systemic disorders that may interfere with the clinical trial.

Subjective Parameters

- *Avipaka*
- *Klama*
- *Uthklesha*
- *Tikta amlodgara*
- *Gourava*
- *Hruthkanta daha*
- *Aruchi*

Assessment Criteria

Effect of treatment was assessed on the basis of changes found in the gradation of the both individual and overall parameters according to their severity before, during and after treatment and analysed statistically.

Table 1: Grading of Subjective parameter [9]

Parameter	G0	G1	G2	G3
Avipāka	No indigestion	Digestion in 9 h	Digestion in 12 h	Digestion ≥24 h
Klāma	No tiredness	After exertion	After routine work	Even after rest
Utkleśha	No nausea	After specific food	After all foods	Persistent, unrelated to food
Tikta–Amlodgāra	No belching	After spicy food	After any food	Unrelated to food
Gaurava	No heaviness	After heavy food	After light food	Even on empty stomach
Hṛt–Kaṇṭha Daha	No burning	After spicy food	After normal food	Even on empty stomach
Aruci	Normal appetite	2 meals/day	1 meal/day	No appetite

Table 2: Treatment Intervention

		Group A	Group B
Sample size		30	30
Medicine		*Simhsasyadi kwatha*	*Patoladipanchanga kwatha*
Dose and time of intake		25ml twice a day (before food)	25ml twice a day (Before food)
Anupana		*Madhu* 10ml	*Madhu* 10ml
Duration		30 days	30 days
Follow-up	During treatment	15th & 30th day	15th & 30th day
	After treatment	60th day	60th day

Criteria for withdrawal

During the course of treatment trail, if any serious condition or any serious adverse events which requires urgent treatment or if any subjects themselves want to withdraw from the study, such subjects may be withdrawn from the trail.

Laboratory investigations

As there are no specific investigations mentioned. The following investigation were carried out to rule out pathology and advised when ever found necessary- CBC, ESR, RBS, PPBS, FBS, LFT, lipid Profile.

Statistical Analysis

SPSS version 20 was used for statistical analysis. Comparative evaluation between groups was done using the Mann-Whitney U Test, while within-group analysis employed the Wilcoxon Signed Rank Test.

Sample Size Estimation

Using the lottery method, 32 of 62 registered subjects were randomly allocated to Group A *(Simhasyadi kwatha)* and 30 to Group B *(Patoladipanchanga Kwatha)*. Due to personal reasons two subjects dropped out of this study, from Group A.

Table 3: Sample size

Type	No. of Patients		Total
	Group A	Group B	
Registered	32	30	62
Completed	30	30	60

OBSERVATION

Table 4

Parameter	Key Findings
Age	26.7% in 31–40 & 41–50 yrs
Gender	Females 68.3%, males 31.7%
Religion	Hindus 86.7%
Education	Graduates 38.3%, SSLC 25%

Occupation	Housewives 33.3%, officials 28.3%
Socio-economic	Middle class 70%
Family history	95% no family history
Diet type	Mixed diet 75%
Ahara Vidhi	*Vishamashana* 33.3%
Rasa Satmya	*Katu* 65%, *Amla* 55%
Onset	Gradual 73.3%, sudden 26.7%
Aggravating period	Afternoon & night 21.7%, afternoon + evening 11.7%
Mental Stress	85% had stress/strain
Addictions	Tea 41.7%, coffee 28.3%, alcohol 6.6%, tobacco 5%
Sleep *(Nidra)*	Disturbed sleep 41.7%
Bowel Habits	Irregular 36.7%
Prakruti	*Vata-Pitta* 51.7%, *Pitta-Kapha* 43.3%
Sara/Satwa/Satmya/Samhanana	Majority *Madhyama* (78–90%)
Abhyavaharana Shakti	*Madhyama* 68.3%, *Avara* 21.7%
Jarana Shakti	Avara 53.3%, Madhyama 46.7%
Agni	*Vishamagni* 61.7%, *Mandagni* 46.7%
Koshta	*Krura* 38.3%, *Madhyama* 56.7%
Bala	*Madhyama* 88.3%, *Pravara* 3.3%, *Avara* 8.3%
Desha	*Anupa Desha* 91.7%
Anubandha Lakshana	*Shirashoola* 20%, *Chardi* 16.7%, *Vibandha* 13.3%, None 43.3%

RESULT

Table 5: Effects of *Simhasyadi Kwatha* and *Patoladipanchanga Kwatha* on the symptoms of *Amlapitta*

Avipaka	**Changes from**	**Mean change**	**Median change**	**% of effect**	**Z-value**	**P-value**
Group A	Before to after treatment	0.8	1.0	62.50	4.3724	0.0001*
Group B	Before to after treatment	0.7	1.0	55.56	3.9199	0.0001*

Klama	**Changes from**	**Mean change**	**Median change**	**% of effect**	**Z-value**	**P-value**
Group A	Before to after treatment	0.7	1.0	52.38	4.0145	0.0001*
Group B	Before to after treatment	0.9	1.0	60.47	4.1069	0.0001*

Utklesh	**Changes from**	**Mean change**	**Median change**	**% of effect**	**Z-value**	**P-value**
Group A	Before to after treatment	1.1	1.0	65.31	4.4573	0.0001*
Group B	Before to after treatment	1.0	1.0	76.92	4.4573	0.0001*

Tikta-Amlodgara	**Changes from**	**Mean change**	**Median change**	**% of effect**	**Z-value**	**P-value**
Group A	Before to after treatment	0.9	1.0	57.78	4.2857	0.0001*
Group B	Before to after treatment	1.1	1.0	68.00	4.6226	0.0001*

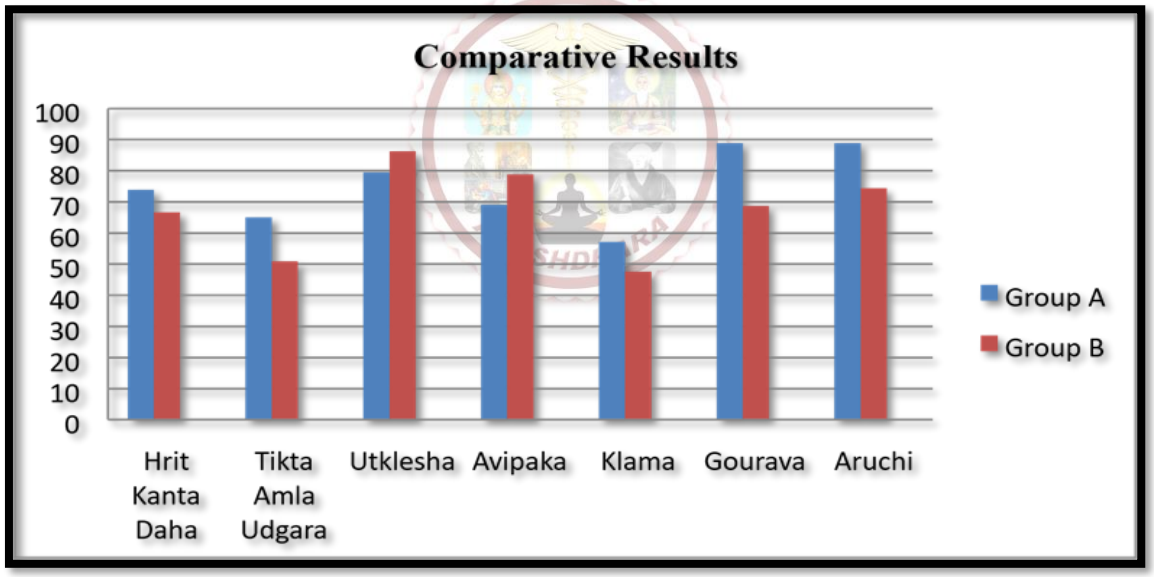
Gourava	**Changes from**	**Mean change**	**Median change**	**% of effect**	**Z-value**	**P-value**
Group A	Before to after treatment	0.6	1.0	57.58	3.6214	0.0001*
Group B	Before to after treatment	0.8	1.0	64.10	4.1069	0.0001*

Hrit-Kantha Daha	**Changes from**	**Mean change**	**Median change**	**% of effect**	**Z-value**	**P-value**
Group A	Before to after treatment	0.9	1.0	61.36	4.2857	0.0001*
Group B	Before to after treatment	1.1	1.0	66.67	4.4573	0.0001*

Aruchi	**Changes from**	**Mean change**	**Median change**	**% of effect**	**Z-value**	**P-value**
Group A	Before to after treatment	0.6	1.0	63.33	3.6214	0.0001*
Group B	Before to after treatment	0.6	1.0	90.00	3.6214	0.0001*

Table 6: Comparison between the percentage relief of Group A and Group B

Criteria	**% relief in Group A**	**% relief in Group B**
Avipaka	62.50%	55.56%
Klama	52.38%	60.47%
Utklesha	65.31%	76.92%
Tikta-Amlodgara	57.78%	68%
Gourava	57.58%	64.10%
Hrit-Kantha Daha	61.36%	66.67%
Aruchi	63.33%	90%
Total % relief	**60.00%**	**68.88%**



DISCUSSION

- *Amlapitta* is a common disorder of the *Annavaha Srotas* caused by *Agnimandya*, leading to *Ama* formation and *Pitta Dosha* vitiation. It is characterized by symptoms such as *Avipaka*, *Tikta-Amla Udgara*, *Hrit-Kantha Daha*, *Aruchi*, *Gourava*, and *Utklesha*. These clinical features closely resemble Gastroesophageal Reflux Disease (GERD), including heartburn, acid regurgitation, indigestion, and nausea.
- The increasing prevalence of GERD due to unhealthy dietary habits, stress, and sedentary lifestyle underscores the contemporary relevance of *Amlapitta*. According to Ayurvedic principles, the pathogenesis of *Amlapitta* begins with *Nidana Sevana* such as *Viruddhahara*, *Vishamashana*, *Adhyashana*, excessive intake of *Katu*, *Amla*, and *Lavana Rasa* predominant foods, irregular food habits, and psychological factors including stress, anxiety, and disturbed sleep. These factors impair *Jatharagni*, leading to incomplete digestion of food and formation of *Ama*. The accumulated *Ama* combines with aggravated *Pachaka Pitta* and undergoes *Shuktapaka*, resulting in increased *Amlata* and *Dravata* of *Pitta.* This pathological

process ultimately manifests as *Amlapitta* with characteristic symptoms involving the *Annavaha Srotas*.

- The principal therapeutic approach in *Amlapitta* focuses on *Agni Deepana, Ama Pachana, Pitta Shamana*, and restoration of normal digestive function. Classical Ayurvedic texts advocate the use of drugs possessing *Tikta* and *Kashaya Rasa*, *Deepana-Pachana* properties, and *Pittashamaka* actions for effective management of *Amlapitta*.

Probable Mode of Action of *Simhasyadi Kwatha*[10]

- *Simhasyadi Kwatha* contains *Vasa* (Adhatoda vasica), *Guduchi* (Tinospora cordifolia), and *Brihati* (Solanum indicum). These drugs predominantly possess *Deepana, Pachana, Ama Pachana, and Pittashamaka* properties. *Guduchi* acts as a potent *Rasayana* and enhances *Agni* while facilitating the digestion of *Ama*. *Vasa* and *Brihati* contribute to *Pitta Shamana* through their cooling and digestive actions.
- The formulation helps restore impaired Jatharagni, prevents further *Ama* formation, and reduces the excessive *Amla* and *Drava* qualities of aggravated Pitta. Consequently, symptoms such as *Avipaka, Aruchi, Tikta-Amla Udgara, and Hrit-Kantha Daha* are effectively reduced. The significant improvement observed in *Avipaka* and *Aruchi* in the present study may be attributed to the strong *Agni*-enhancing and digestive actions of *Simhasyadi Kwatha.*

Probable Mode of Action of *Patoladipanchanga Kwatha*[11]

- *Patoladipanchanga Kwatha* consists of *Patola* (Trichosanthes dioica), *Nimba* (Azadirachta indica), *Amalaki* (Emblica officinalis), *Haritaki* (Terminalia chebula), and *Bibhitaki* (Terminalia bellirica). The formulation is dominated by *Tikta* and *Kashaya Rasa*, *Sheeta Virya*, *Deepana-Pachana*, *Ama Pachana*, and *Pittashamaka* properties.
- *Patola* and *Nimba* effectively reduce aggravated *Pitta* and relieve burning sensations. *Amalaki* provides *Rasayana* and gastroprotective effects, while *Haritaki* and *Bibhitaki* improve digestion, facilitate *Vatanulomana*, regulate bowel function, and aid in the elimination of *Ama*. Through these actions, the formulation interrupts the *Samprapti* of *Amlapitta* by correcting *Agnimandya*, reducing *Ama* accumulation, and normalizing *Pitta*.
- The comparatively greater percentage relief observed in symptoms such as *Tikta-Amla Udgara*, *Hrit-Kantha Daha*, *Gourava*, and *Utklesha* may be due to the strong *Pitta*-pacifying and detoxifying properties of *Patoladipanchanga Kwatha*.

Comparative Insights

- *Simhasyadi Kwatha* is more focused on *Pitta* pacification and alleviation of burning sensations due to its *Sheeta, Snigdha*, and *Madhura Vipaka* properties.
- *Patoladi Panchanga Kwatha* emphasizes *Ama Pachana* and detoxification through *Tikta-Kashaya Rasa* and *Ruksha Guna*.
- Both formulations restore *Agni*, pacify *Pitta*, digest *Ama*, and relieve cardinal symptoms of *Amlapitta* including *Hrit-Kantha Daha*, *Amlodgara*, *Aruchi*, *Avipaka*, and *Gourava*.
- *Kwathas* are administered before meals *(Aharakala Purva)*[12] to optimize *Deepana* and *Pachana* actions. This timing enhances *Jatharagni*, prevents improper digestion, and reduces *Ama* formation.
- Administration with *Madhu* (honey) augments *Deepana-Pachana* effects, improves assimilation, and pacifies *Pitta* and *Vata*. Honey also reduces the irritant potential of bitter or astringent herbs, ensuring smoother absorption and enhanced therapeutic efficacy.

CONCLUSION

The present study observed a higher prevalence among individuals aged 31–50 years, females, and subjects with irregular dietary practices, *Katu-Amla* predominant diet, disturbed sleep, and mental stress. The clinical benefits observed in both groups may be attributed to the *Deepana, Pachana, Ama Pachana, and Pittashamaka* properties of the constituent drugs, which help correct *Agnimandya*, digest *Ama,* pacify aggravated *Pitta,* and restore the normal functioning of the *Annavaha Srotas*.

Both *Simhasyadi Kwatha* and *Patoladipanchanga Kwatha* produced statistically significant improvement in the clinical manifestations of *Amlapitta* after 30 days of treatment. Intergroup analysis revealed no statistically significant difference between the two groups, indicating comparable therapeutic efficacy. No adverse drug reactions were reported during the study period, indicating that both formulations are safe and well tolerated.

Based on the findings of the present study, the alternate hypothesis (H1) is accepted, confirming that both *Simhasyadi Kwatha* and *Patoladipanchanga Kwatha* are effective in the management of *Amlapitta,* with no statistically significant difference between their therapeutic outcomes.

Limitations of the Study

- The study was conducted on a relatively small sample size, which may limit the generalizability of the findings.

- The duration of treatment and follow-up was limited to 30 days.
- Assessment was primarily based on subjective clinical parameters.
- A few participants reported difficulty in adhering to *Pragbhakta Oushadha Sevana Kala* and experienced palatability-related issues with the *Kwatha* formulations.

Future Scope

- Further multicentric studies with larger sample sizes and longer follow-up are required to validate the present findings.
- Inclusion of objective assessment tools such as endoscopy and gastric pH monitoring may provide stronger clinical evidence.
- Pharmacological studies and evaluation of alternative dosage forms and *Anupanas* may further enhance the therapeutic application of these formulations.

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