



# Journal of Ayurveda and Integrated Medical Sciences

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An International Journal for Researches in Ayurveda and Allied Sciences





#### ORIGINAL ARTICLE May 2024

# A comparative clinical study to assess the effect of Amlapitta Vinashaka Yoga and Pantoprazole with Sheetali Pranayama in the management of Amlapitta

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# ABSTRACT

Background: In this modern era there has been an unprecedented increase of incidences related to GI system due to marked change in life style. Diet pattern, behavioral pattern & mental stress & strain, these multiple factors lead to a clinical condition known as the Amlapitta. Symptoms of Amlapitta as explained in Ayurveda are nearer clinical entity with symptoms of hyperacidity Gastro-intestinal disorder mentioned in modern science. Aim and Objectives: This study aims to evaluate the efficacy of Amlapitta Vinashaka Yoga and Pantoprazole with Sheetali Pranayama. Materials and Methods: An open Randomized Comparative clinical study was conducted in 45 Patients. Patients were randomly selected in to 3 groups. Group A - 15 patients were treated with Amlapittavinashaka Yoga and Sheetali Pranayama, Group B - 15 patients were treated with Pantoprazole and Sheetali Pranayama and Group C - 15 patients were treated with Sheetali Pranayama & placebo. Results: The overall study suggestive of in group A, 7% patients showed moderate relief, 53% patients showed marked response to treatment where as 40% patients showed complete Response to the treatment. In group B 7% patients showed moderate response to treatment, 80% patients showed marked response to the treatment, where as 13% patients showed complete relief to the treatment. In group C 20% patients showed mild relief, 47% patients showed moderate response to treatment where as 33% patients showed marked response to the treatment. Conclusion: The study revealed that the study drug Amlapitta Vinashaka Yoga and regular practice of Sheetali Pranayama schedule 10 cycles at afternoon before meal is effective in treating Amlapitta (Hyperacidity).

Key words: Amlapitta, Amlapitta Vinashaka Yoga, Ayurveda, Hyperacidity, Pantoprazole, Sheetali Pranayama.

#### **INTRODUCTION**

In recent years there has been an unprecedented increase of incidences related to gastro intestinal system due to change of lifestyle. And it can be

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Submission Date: 13/03/2024 Accepted Date: 21/04/2024

Access this article online			
Quick Response Code			
	Website: www.jaims.in		
	DOI: 10.21760/jaims.9.5.3		

described as a disease of modernization due to unhealthy eating habits, mental stress and strain. Hyperacidity is probably a commonest digestive disorder.

In a demographic survey, its prevalence range observed is about 11% to 38.8% of world population.<sup>[1]</sup>

By prolonged use of drugs such as aspirin, ibuprofen, muscle relaxants etc. which can irritate the esophagus and cause heart burn.<sup>[2]</sup> Along with this if there is an increased and frequent consumption of tea, coffee, tobacco, smoking and alcohol which would result in incompatibility of food and ends in gastric related complaints such as nausea, vomiting and heart burn etc.

Treatment is directed at the cause but often includes acid suppression. If left untreated it leads to several

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life-threatening complications such as ulceration, perforation, gastrointestinal bleeding and adenocarcinoma.

Modern treatment includes PPIs, H2 blockers, antacids etc. But these have their own limitations. However, the antacids are among the one of the most widely used medicine all over the world. The US Food and Drug Administration (FDA) warned that there is increased risk of fractures with the use of Proton Pump Inhibitors (PPIs) including Esomeprazole, Omeprazole, Pantoprazole.<sup>[3]</sup>

As per Modern interpretation symptoms of Hyperacidity can be correlated to *Amlapitta*. Description of disease *Amlapitta* and its *Chikitsa* has been found in detail in classical Ayurvedic texts like *Kashyapa Samhita*,<sup>[4]</sup> *Yogaratnakar*<sup>[5]</sup> and *Bhaisajya Ratnawali*.<sup>[6]</sup> In *Brihatrayees*, *Amlapitta* was not considered or grouped under any specific disease, but the symptoms are mentioned.

Amlapitta is one of the common problems of Annavaha Srotas caused due to Mandagni and vitiation of Pachaka Pitta. Increase in Ama and Drava Guna of Pachaka Pitta gives rise to Amlapitta with symptoms as Amla-Tiktaudagar, Hrut-katha Daha, Aruchi, Avipaka, Klama<sup>[7]</sup> etc.

Hence, we shall consider the *Nidana Parivarjana* and *Samprapti Vighatana* to overcome the disease<sup>[8]</sup> and the drug selected to control is *Amlapitta Vinashaka Yoga* described in *Bhaishajya Ratnavali, Amlapitta Adhikara*, which contains *Pathya*, *Bhringaraj* and *Jeerna Guda* having *Tikta* and *Kashaya Rasa* which are *Agnideepaka*, *Pittashamaka*, *Anulomana* properties.<sup>[9]</sup>

*Sheetali* is one of the type of *Pranayama* which helps the people who suffer from acidity or any *Pittajanya Rogas*, by the regular practice.<sup>[10]</sup>

Hence a clinical study to assess the effect of *Amlapitta Vinashaka Yoga* along with *Sheetali Pranayama* in the management of *Amlapitta* is being undertaken.

#### **OBJECTIVES OF STUDY**

1. To study the effect of *Sheetali Pranayama* in *Amlapitta*.

- 2. To study the combined effect of *Amlapitta Vinashaka Yoga* and *Sheetali Pranayama* in *Amlapitta*.
- 3. To study the combined effect of Pantoprazole and *Sheetali Pranayama* in *Amlapitta*.

#### **MATERIALS AND METHODS**

#### **Selection of Patients**

#### **Inclusion Criteria**

- 1. Patients of *Amlapitta* with classical symptoms like *Tikta Amlodgara, Hrit Kantha Daha, Aruchi.*
- 2. Age between 16-40 years.
- 3. Patients of *Amlapitta* without any critical complication.

#### **Exclusion Criteria**

- 1. Past or present history of Duodenal or Peptic ulcer.
- 2. Evidence of Malignancy.
- Patient taking drug such as NSAIDs which is supposed to increase acid production and gastric ulcerations.
- 4. Present history of esophageal varices and hematemesis.
- 5. Pregnancy or lactating Mother
- 6. Low Blood Pressure

#### Drugs used

#### Table 1: Composition of trial drug

SN	Drug Name	Latin Name	Part Used	Quantity
1.	Pathya	Terminalia chebula	Phala Majja	1 Part
2.	Bhringaraja	Eclipta alba	Leaves	1 Part
3.	Jeerna Guda	Jaggery		1 Part

#### **Preparations of medicine**

Amlapitta Vinashaka Yoga was prepared in the Dept. of Rasa Shastra & Bhaishajya Kalpana of S.J.G. Ayurvedic Medical College, Koppal as mentioned in

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classics. Pantoprazole drug was been taken, which is available in market.

# Table 2: Study design: Open randomized comparative clinical trial

Groups	Group A	Group B	Group C
Sample size	15 patients	15 patients	15 patients
Drug	Amlapitta Vinashaka Yoga and Sheetali Pranayama	Pantoprazole and Sheetali Pranayama	Placebo and Sheetali Pranayama
Dose	6gm BD	20mg BD	6gm BD
Time of administration of drug	Before Food	Before Food	Before Food
Sheetali Pranayama	10 cycles at afternoon Before meal	10 cycles at afternoon Before meal	10 cycles at afternoon Before meal
Duration	15 Days	15 Days	15 Days

## **Parameters of Study**

#### **Assessment Criteria**

Improvement in Subjective Parameters of *Amlapitta* was been assessed before & after the treatment.

# **Table 3: Subjective Criteria**

Α.	Subjective Parameters
1.	Tiktaamlodgara (Acid Sour Eructation).
2.	<i>Hrit-Kanthadaha</i> (Burning Sensation in Throat& chest Region).
4.	Aruchi (Nausea).
5.	Avipaka (Dyspepsia).

## **Assessment of variables**

Patients were assessed by using Subjective parameters and severity of clinical conditions before, after treatment and follow up.

# **OBSERVATION AND RESULTS**

Table 4: Showing comparative effect of therapy onsubjective parameters in Group A, Group B & GroupC.

Overall Response	Group A		Group B		Group C	
Response	Mean	SD	Mean	SD	Mean	SD
Tikta Amlodgara	1.53	0.516	1.67	0.488	1.73	0.458
Hrit Kanta Daha	1.20	0.414	1.40	0.507	1.73	0.594
Aruchi	1.53	0.516	1.60	0.507	1.80	0.561
Avipaaka	0.87	0.352	1.07	0.458	1.40	0.507

# Table 5: Showing the overall effect of study on bothGroup A, Group B & Group C

Overall Response	Group A	%	Group B	%	Group C	%
Unchanged	0	0%	0	0%	0	0%
Mild Response	0	0%	0	0%	3	20%
Moderate Response	1	7%	1	7%	7	47%
Marked Response	8	53%	12	80%	5	33%
Complete Response	6	40%	2	13%	0	0%
Total	15	100%	15	100%	15	100%

#### DISCUSSION

Majority of patients were from age group of 32-40 years. This suggests that persons are with struggle of life giving them more stress. This age is also the age of *Pitta* predominance.

*Amlapitta* showed its direct impact on *Annavaha Srotasa*. *Agnimandya* was present in majority of patients. Present lifestyle that has disturbed the food

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habits gives rise to Agnimandya, Vidagdhajirna, and finally leads to Amlapitta. Socio-economic condition, mental stress, and strain play an important role in causing and aggravating the disease.

Among all *Pranayamas, Sheetali Pranayama* is choice for the clinical condition that are related with the gastrointestinal tract, *Sheetali* is one of the types of *Pranayama* which helps the people who suffer from acidity or any *Pittajanya Rogas*. It has cooling and soothing effect on the body. *Sheeta Guna* of *Vata Dosha* is increased, it may reduce extra heat and balance *Pachakpitta*. By this effect *Daha* will be diminished and increase the *Jataragni*.

Amlapitta Vinashaka Yoga which contains Pathya, Bhringaraj and Jeerna Guda having Tikta and Kashaya Rasa which are Agnideepaka, Pittashamaka, Anulomana properties.

Standard drug (Pantoprazole) was found to be quite effective in providing immediate relief from symptoms such as *Daha*, *Amlodgara*, and *Shula* (pain). Pantoprazole acts by inhibiting the secretion of hydrochloric acid in the stomach by specific action on the proton pumps of the parietal cells. However, during follow-up after 1 month, there is reduction in percentage relief and relapse of symptoms occurs while treatment with ayurvedic palliative medicine more sustained relief was found.

The overall study suggestive of in group A, 7% patients showed moderate relief, 53% patients showed marked response to treatment where as 40% patients showed complete response to the treatment. In group B, 7% patients showed moderate response to treatment, 80% patients showed marked response to the treatment, where as 13% patients showed complete relief to the treatment. In group C, 20% patients showed mild relief, 47% patients showed moderate response to treatment where as 33% patients showed marked response to the treatment.

## CONCLUSION

In recent years there has been an unprecedented increase of incidences related to gastro intestinal system due to change of lifestyle. And it can be described as a disease of modernization due to unhealthy eating habits, mental stress and strain. Hyperacidity is probably a commonest digestive disorder. By considering overall result, in the present study the effect of *Sheetali Pranayama* with giving medicine was more beneficial.

In Group A (*Amlapitta Vinashaka Yoga* with *Sheetali Pranayama*), 7% patients showed Moderate relief, 53% patients showed Marked response to treatment where as 40% patients showed complete Response to the treatment. The standard drug (Pantoprazole) was found to be quite effective in providing immediate relief from symptoms such as *Daha*, *Amlodgara*, and *Shula* (pain). However, during follow-up after 1 month, there is reduction in percentage relief and relapse of symptoms occurs while treatment with Ayurvedic palliative medicine more sustained relief was found.

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**How to cite this article:** Channamma, Prabhu. C. Nagalapur, Chandrashekaraddi S. Karamudi. A comparative clinical study to assess the effect of Amlapitta Vinashaka Yoga and Pantoprazole with Sheetali Pranayama in the management of Amlapitta. J Ayurveda Integr Med Sci 2024;5:16-20. http://dx.doi.org/10.21760/jaims.9.5.3

Source of Support: Nil, Conflict of Interest: None declared.

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