



## Research Article

### EFFECT OF *NISTHUSHAYADIKWATHA* AND *PHALATRIKADI KWATHA* IN *AMLAPITHA* - A RANDOMISED COMPARATIVE CLINICAL STUDY

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#### ABSTRACT

*Amlapitta* may be a clinical entity manifesting within the *Annavaha Srotas*. *Kashyapa* and *Madhava* have described this disease thoroughly. *Amlapitta* has become quite common because of the change within the food and life styles, sophistication and a stressful life. It is characterized by *Avipaka*, *Klama*, *Tiktodhgara*, *Amlodhgara*, *Gaurava*, *Hritkanthadaha* and *Aruchi* indicating the *Vikruthi* of *Pachakapitta*, *Kledakakapha* and *Samanavata*. The etiological factors and therefore the symptomatology manifested relate *Amlapitta* to diseases mentioned under Acid Peptic Disorders. *Nistushayadi Kwatha* and *Phalatrikadi kwatha* were selected. The main objectives of the study are to study and compare the effect of *Nistushayadi Kwatha* and effect of *Phalatrikadi kwatha* in the management of *Amlapitta*.

A total of 40 patients who fulfilled the inclusion criteria were selected, and randomly assigned into two groups i.e., Group A and Group B, comprising of 20 patients each. Group A and Group B were administered *Nistushayadi kwatha* and *Phalatrikadi Kwatha* respectively for 30 days. Both the groups were advised *Pathya Ahara*. They were followed up after every 10<sup>th</sup> days. After the intervention the *Samanya Lakshana* of *Amlapitta* were observed, recorded and assessed. The overall assessment of both the groups, where group A receives *Nistushyadi kwatha* and group B *Phalatrikadi kwatha* shows promising improvement in the subjective parameters. Assessment was done using unpaired 't' test between these two groups, the result was not quite statistically significant which means there is no much difference in the efficacy of these two formulation in the management of *Amlapitta*. Both the formulations shown nearly same outcome in the improvement of disease parameter. The reduction in the symptoms were started to be noticed by 7<sup>th</sup> day where the patients had reduction in *Hrutkantha Daha*, *Aruchi*, *Kanthadaha* and *Angagourav*. These symptoms resolved by 30<sup>th</sup> day.

**KEYWORDS:** *Amlapitta*; *Nistushayadi kwatha*; *Phakatrikadi Kwatha*.

#### INTRODUCTION

The condition where the *Ahara rasa* after reaching to *Amashaya* cause *Vidaghdha* of *Pitta* is called *Amlapitta*. It is a disease of *Annavaha Srotas* and is more common in the present scenario of unhealthy diets and regimen. It is the disease, where *Vidaghdha* and *Amla Yukta Rasa* leading to *Anna Vaha Sroto Dushti* causes symptoms like *Avipaka*, *Klama*, *Tikta Amlodhgara*, *Gaurava*, *Hrtkanta Daha*, and *Aruchi*<sup>[1]</sup> *Amlapitta* can be correlated with Hyperacidity or Acid Dyspepsia.

Importance of food has been explained by *Acharya Charaka*<sup>[2]</sup> which clearly states that all the *Sharira*, *Manasika Sukha Dukha* completely depends on food that we intake. *Ahita Anna Bhojana* disturbs

*Agni*. Thus disturbed *Agni*, in turn disturbs the entire equilibrium of the body there by leading to many *Vikaras*. *Shodana*, *Shamana* and *Nidana Parimarjana* are the main line of treatment adopted by our *Acharyas*<sup>[3]</sup>. The management in modern science is usage of antacids, Proton Pump Inhibitors [PPIs], H2 receptors. Antacids works by neutralizing the amount of acid in the stomach<sup>[4]</sup>. Food and Drug Administration (FDA) warns that there is certain antacids cause an increased risk of fractures<sup>[5]</sup>. Long term use of these medicines produces vomiting, diarrhoea, weakness, low blood pressure, skin rashes<sup>[6]</sup>. Hence it's the need of the hour to develop better medicament to manage this condition. As these

medications doesn't give a permanent remedy and due to its high recurrence chances it is the need of the hour to find measures to overcome this burning problem through Ayurvedic system of medicine. The drug selected for the study aiming to reduce the *Vidagdha* and other *Laxanas* of *Amlapitta* are *Nistushayadi Kwatha*<sup>[7]</sup> and *Phalatrikadi Kwatha*<sup>[8]</sup>.

**MATERIALS AND METHODS**

A randomized comparative clinical study is done with a sample size of Total 40 patients selected in 2 groups. Group A: Patients will receive *Nistushayadi Kwatha* and Group B. Patients will receive *Phalatrikadi Kwatha*.

**Inclusion criteria**

1. Patients presenting with *Lakshanas* of *Amlapitta*.
2. 18 to 60 yrs of patients
3. Patients of either sex will be taken for study.

**Exclusion criteria**

1. Patients suffering from other systemic illness which interfere with the course of treatment.
2. Below 18yrs and above 60yrs.
3. Diagnosed case of Ulcerative Colitis, Perforated Ulcer, Crohn's disease
4. Ca stomach.

**Composition of trial drugs**

**Table 1: Nistushayadi Kwatha**

S.No.	Ingredients	Quantity
1.	<i>Nistu [Yava]</i> (Dehusked Barley)	1 Part
2.	<i>Vasa</i>	1 part
3.	<i>Amlaki</i>	1 part
4.	<i>Trijatakachoorna</i>	1 part
5.	Honey	1 part

**Table 2: Phalatrikadi Kwatha**

S.No.	Ingredients	Quantity
1.	<i>Haritaki</i>	1 Part
2.	<i>Vibhataki</i>	1 part
3.	<i>Amlaki</i>	1 part
4.	<i>Patola</i>	1 part
5.	<i>Kiratatikta</i>	1 part

A required dry drug for preparing *Nistushayadi kwatha* and *Phalatrikadi Kwatha* was procured from local market and pharmacy; taxonomist will authenticate it. *Churnais* prepared as per standard method. *Nistushayadi kwatha* and *Phalatrikadi Kwatha* was given to the patients along with respective *Prakshepakadravya* and method of *Kwatha* preparation is advised to prepare at home.

**The Total Duration of Study:** 30days (with follow-up on every 10<sup>th</sup> day). *Nistushayadi Kwatha* and *Phalatrikadi Kwatha* were given to patients 48 ml twice a day before meals.

**Table 3: Subjective parameters and Criteria for the treatment are following**

Parameter	No symptoms (0)	Mild (1)	Moderate(2)	Severe(3)
<i>Avipaka</i> (Indigestion)	Presence of all <i>Jeernahar Laxanas</i>	Presence of any 4 <i>Jeernahar Laxanas</i>	Presence of any 2 <i>Jeernahar Laxanas</i>	No <i>Jeernahar Laxanas</i>
<i>Amlodgar</i> (Sour belching)	Absent	Appears 2-3 times/ days on consumption of food	Appears 4-6 times/days on consumption of any type of food	Appears more than 6 times/days on consumption of food
<i>Angagorava</i> (Fatigue)	Absent	Feel of heaviness in <i>Udara</i>	Feel of heaviness associated with <i>Avipaka</i>	Feel of heaviness associated with <i>Klama</i>
<i>Kanthadaha</i> (Burning sensation in the chest)	Absent	Burning sensation in the throat region	Associated with <i>Utklesha</i>	Associated with Gastric regurgitation
<i>Hritdaha</i> (Burning sensation in cardiac region)	Absent	Retrosternal Discomfort	Associated with pain	Associated with Gastric regurgitation
<i>Aruchi</i> (Anorexia)	Absent	Loss of interest in intake of food	Aversion to the food	Nausea and sometimes Vomiting after intake of food

**RESULTS**

In this study, effects of *Nistushayadi Kwatha* and *Phalatrikadi Kwatha* in the management of *Amlapitta* were registered for clinical trial and were categorized randomly into two groups consisting of 20 patients in each group according to inclusion criteria and each patient was observed and histories were noted, examinations were done thoroughly and noted.

**Table 4: Chief complaints wise distribution of 40 patients of *Amlapitta***

Chief complaints	No of patients		Total No. of patients (40)	Percentage
	Group A	Group B		
<i>Aruchi</i>	20	20	40	100
<i>Amlodgara</i>	20	19	39	97.5
<i>Kantha daha</i>	20	18	38	95
<i>Hrit daha</i>	20	18	38	95
<i>Angagorva</i>	20	19	39	97.5
<i>Avipaka</i>	19	17	37	92.5

**Table 5: Effect of *Nistushayadi Kwatha* and *Phalatrikadi Kwatha* in the Management of *Amlapitta***

Sl.no	Criteria	<i>Nistushayadi Kwatha</i> (Group A)	<i>Phalatrikadi Kwatha</i> (Group B)
1.	<i>Aruchi</i>	61.53	59.37
2.	<i>Amlodgara</i>	56.41	55.17
3.	<i>Kanhdaha</i>	58.82	44.44
4.	<i>Hritdaha</i>	65.38	53.84
5.	<i>Angagorava</i>	56.25	50
6.	<i>Avipaka</i>	54.16	50

**Table 6: Comparisons between Group A and Group B**

Parameters	Reduction In Mean		SD		SEM		SED	T value	p Value	Significance at p < 0.05
	Group A	Group B	Group A	Group B	Group A	Group B				
<i>Aruchi</i>	1.2	0.95	0.41	0.50	0.09	0.11	0.142	1.759	0.086	Not quite statistically significant
<i>Amlodgara</i>	1.11	0.85	0.45	0.52	0.1	0.117	0.154	1.689	0.099	Not quite statistically significant
<i>Kantdaha</i>	1	0.6	0.46	0.6	0.103	0.134	0.169	2.366	0.0231	Statistically significant
<i>Hritdaha</i>	0.85	0.7	0.37	0.57	0.82	0.128	0.830	0.1807	0.857	Not statistically significant
<i>Angagourava</i>	0.9	0.75	0.55	0.44	0.124	0.099	0.159	0.945	0.350	Not statistically significant
<i>Avipaka</i>	0.65	0.45	0.49	0.51	0.109	0.114	0.158	1.268	0.212	Not statistically significant

**Table 7: Overall assessment of the treatment between both groups**

Parameters	Reduction in Mean		SD		SEM		SED	T value	p Value	Significance at p< 0.05
	Group A	Group B	Group A	Group B	Group A	Group B				
Overall Assessment Between the groups	0.9517	0.7167	0.1965	0.1780	0.0802	0.0726	0.108	2.1713	0.0551	Not quite statistically significant

The overall assessment of both the groups, where group A receives *Nistushyadi kwatha* and group B *Phalatrikadi kwatha* shows promising improvement in the subjective parameters. Assessment was done using unpaired 't' test between these two groups the result was not quite statistically significant which means there is no much difference in the efficacy of these two formulation in the management of *Amlapitta*. Both the formulations shown nearly same outcome in the improvement of disease parameter.

#### DISCUSSION

Total 47 patients of *Amlapitta* were registered. Among them 40 patients completed the study and 4 were dropouts. Based on the inclusion criteria the patients were selected for the study and randomly assigned into two groups comprising of 20 in each. The inclusion criteria and exclusion criteria were made giving due consideration to *Samanya Lakshana* of *Amlapitta*. The present study was conducted in *Jangala Desha*. 20 patients in each group and remaining 4 patients (2 in group A and 2 in group B) discontinued the treatment. The reason for discontinue is unknown.

The assessment of results were done by assessing the subjective parameters on grading by using specific grades as mentioned earlier in the clinical study. Assessment was done before the treatment, after the treatment and after the follow up of one month. The effect of the treatment shows promising improvement in the subjective parameters. By analyzing the result of the treatment on the basis of different parameters such as *Aruchi*, *Amlodghara*, *Kanthdaha*, *Hrutdaha*, *Angaurava* and *Avipaka* it shows that *Nistushyadi kwatha* and *Phalatrikadi kwatha* have good result and statistical significant shows there is no much difference in the efficacy of these two formulations in the management of *Amlapitta*.

#### CONCLUSION

The present study entitled, Effect Of *Nisthushayadi kwatha* and *Phalatrikadi Kwatha* In *Amlapitha*- A Randomized Comparative Clinical Study was carried out on 40 patient of *Amlapitta*.

The present study was a comparative clinical study with pre-test and post-test design wherein 40 patients of irrespective of sex, religion, work and socio-economic status of *Amlapitta* were selected and randomly assigned into two groups comprising of 20 patients in each group. Patients of Group A were administered *Nistushsyadi Kwatha* and patients of Group B were administered *Phalatrikadi Kwatha* in the dose of 48ml.

The study revealed that;

Maximum patients were female patients belonging to lower middle socio-economic status, Hindu religion, married, having mixed diet presenting with the maximum *Samanya Lakshana* of *Amlapitta*, with average duration of 1 to 2 years. *Nistushayadi Kwatha* and *Phalatrikadi Kwatha* are effective in *Amlapitta* to achieve the results as *Shamana Prayoga*.

The overall assessment of both the groups, where group A receives *Nistushyadi kwatha* and group B *Phalatrikadi kwatha* shows promising improvement in the subjective parameters. Assessment was done using unpaired 't' test between these two groups the result was not quite statistically significant which means there is no much difference in the efficacy of these two formulation in the management of *Amlapitta*. Both the formulations shown nearly same outcome in the improvement of disease parameter.

The reduction in the symptoms were started to be noticed by 7<sup>th</sup> day where the patients had reduction in *Hrutkantha Daha*, *Aruchi*, *Kanthadaha* and *Angagourav*. These symptoms resolved by 30<sup>th</sup> day. The *Avipaka* appeared in 2patients during the follow-up period and *Amlodhgara* for 1 patient.



### Pictures of Experimental Study



Ingredients of Nishtushayadi kwatha Ingredients of Phalatrikadi kwatha

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