

Randomized open control clinical study to evaluate the efficacy of “Amalakyadiloha” Orally with comparison to “Amlapittantakloha” in the management of Urdhwaga Amlapitta in age group from 18 to 55 years.

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Abstract –

Aacharya kashyap has first of all mentioned the disease *amlapitta* in separate chapter¹. *Aacharya Kashyap* has also analyzed *Amlapitta* based on dosha; however, *Kashyap* held that *Amlapitta* is created by variation of *tridosha* caused *mandagni* leading to *vidhagdajirna*, which in turn manifests as *Amlapitta*. *Madhavkar* has given its classification on the basis of *dosha gati*².

According to *Aacharya Charak*, *manas bhava* like *chinta* (worry), *shok* (grief), *krodha* (rage) and *bhaya* (fear) cause the *agni* to variate, which in turn aggravates the illness³. In *Charak Samhita*, *Amlapitta* has not been described as a disease. He has mentioned that when *amavisha* is directly mixed with *pitta* and *Amlapitta* will developed⁴.

AIM :

To study the therapeutic effect of oral administration of “*Amalakyadiloha*” Orally with comparison to “*Amlapittantakloha*” in the management of *Urdhwaga Amlapitta*.

OBJECTIVES:

To see the effect of ‘*Amalakyadiloha*’ in sign and symptoms of *Urdhwaga Amlapitta* i.e. *Avipaka*, *Aruchi*, *Tiktamloudgar*, *Hrutkanthadaha*, *Utklesh*, *Chardi*, *Gaurav*, *Klama*.

Material and Methods –

Total 60 patients of *Amlapitta* selected randomly which is then divided into two equal Groups i.e. 30 patients in each group. Giving intervention by ‘*Amalakyadiloha*’ orally locally for group A and ‘*Amlapittantakloha*’ locally for group B for 45 days treatment and follow up taken for post therapy 45 days. Analysis of all patients were done and after that Result and conclusion were drawn.

Result and Conclusion –

All symptoms were significantly reduced in Group A and Group B (Wilcoxon Signed Ranks test; P<0.05). In Trial group (*Amalakyadiloha*) average % relief was 66.79%. In Control Group (*Amlapittantakloha*) average % relief was

70.12%. On the basis of overall percent relief, Oral administration of *Amalakyadiloha* is less effective than *Amlapittantakloha* in the management of *Urdhwaga Amlapitta* to reduce *Tikta-amla udgar, Hrit Kantha daha, Utklesha, Chardi, Aruchi, Udarshool and Gaurav*.

Keyword – *Amalakyadiloha, Amlapittantakloha, GERD (Gastro Esophageal Reflux Disease)*

Introduction –

Ayurveda teaches people how to live their lives and it is the oldest science and art of living. It's laws and regulations state that one must adhere to *Dincharya, Ritucharya, Ratricharya, Swasthavrutta* and other practices if he wants to live a life free from disease. Ayurveda's main aim is

स्वस्थस्य स्वास्थ्यरक्षणमातुरस्य विकारप्रशमनं च | च.सु. 30/26
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Prevent health of healthy person and to treat the diseased person. Ayurveda also promotes humanity's physical, mental, social and spiritual well being.

The 21st century has seen a significant shift in human lifestyle due to urbanization and industrialization. He needs to confront his bad eating habits, which include consuming fast food, packing food, ignoring *ritucharya* and *dincharya*, smoking, drinking alcohol and getting inadequate sleep, all of which can lead to diseases like GERD, PUD etc. and *Amlapitta* is one of them.

निरुक्ती:- अम्लगुणोद्विक्रतम् पित्तम् अम्लपित्तं | मा.नि.51/1⁶

Amlapitta is a disease of *rasavaha* and *annavaha* Strotas caused due to vitiation of *pitta* and *kapha* by *aam*. When *amla* and *drava guna* of *pitta dosha* become exaggerated, then it causes illness. *Agni* is the important concept of Ayurveda. Variations in *Agni* status leads to various diseases. *Aacharya Charaka* first described *Agni* in detail in *Grahani*

*Adhyay*⁷. Vitiation in *Agni* leads to *Shukta paka* (undigested material) & causes various diseases such as *Amlapitta*⁸.

रोगाः सर्वेऽपि मन्दङ्गनौ सुतरामुद्राणि तु ।

अजीर्णात्मलिनैश्चान्नैजयन्ते मलसंचयात् । अ. ह.नि 12/1⁹

Acharya Vagbhata said that vitiation of *Agni* is the main cause of any diseases. The primary causes of any sickness are *Mithya Aahar, Mithya Vihar* and *Pradnyaparadh*. *Amlapitta* is regarded as gastrointestinal disorder that results in symptoms such as *Avipaka, Klama, Aruchi, Tikta-amlaudgar, Gaurav, Hrit-kanthadaha, Chardi, Udarshool* and *Shirshool*. This suppression of *jatharagni* (gastric fire) is caused by increased *amla guna* and *drava guna* (liquidity) of *vidhagdha pachak pitta*. *Amla* and *Katu ras* is natural property of *pitta* according to *Aacharya Charaka*¹⁰.

The *Sushruta Samhita* does not contain the word “*Amlapitta*” however *Amilika* has been identified as the illness brought on by an overuse of *lavana*¹¹.

आम्लपित्तं त्रिधाप्रोक्तं वातेन श्लेष्मस्तथा तृतीयं श्लेष्मवाताभ्यां । (शा. पु. ७/१००)⁽¹²⁾

Aacharya Sharangadhara has classified *Amlapitta* into three categories: *vataja, kaphaja* and *kaphavataja*. In a demographic survey, it's prevalence range observed is about 11% to 38.8% of world Population¹³. Malaysia, Mexico, Spain and Yemen reported figures on the top quartile in prevalence, whereas the Asian countries reported prevalence rates in the lowest quartile. It is reported that 7.6% of Indian subjects GERD symptoms¹⁴.

Aim and Objective:

AIM :

To study the therapeutic effect of oral administration of “*Amalakyadiloha*” Orally with comparison to “*Amlapittantakloha*” in the management of *Urdhwaga Amlapitta*.

OBJECTIVES:

- 1) To study the disease *Urdhwaga Amlapitta*.
- 2) To study therapeutic effect of *Amalakyadiloha* in the management of *Urdhwaga Amlapitta*.
- 3) To see the effect of *Amalakyadiloha* orally in the signs and symptoms of *Urdhwaga Amlapitta* which is *Avipaka, Aruchi, Tiktamloudgar, Hrutkanthadaha, Utklesh, Chardi, Gaurav, Klama*.
- 4) To compare the effect of *Amalakyadiloha* with *Amlapittantakloha* in the management of *Urdhwaga Amlapitta*.

Material And Methods-

Study Design: Prospective, randomized Controlled, open labelled clinical study. Place PG Department of Kayachikitsa Laxmanrao Kalasapurakar Ayurved College, Yavatamal, affiliated with D.M.M. Ayurved College, Yavatamal

Duration: 45 Days drug intervention and 45 days follow up.

Selection Of Patient –

a) Inclusive Criteria –

- 1) Patients above 18 years to 55 years

2) Patients having sign and symptoms of *Urdhwaga amlapitta* such as *tikta-amlodgara, avipaka, klama, Hrit-kantha daha, utklesha*.

3) Irrespective of gender.

4) Irrespective of caste, religion

5) Patients belonging to any socio-economic class

B) Exclusive Criteria –

1) Patient not willing to participate in the trail.

2) Patient below the age 18 years and above 55 years.

3) Gastric ulcer

4) Perforated ulcer

5) Duodenal ulcer

6) Cancer of any grade of oesophagus

7) Abdominal Koch's

8) Pregnant ladies and lactating mother

9) Associated with any other serious systemic disease or complication

10) Diabetic melitus and insipidus

11) Patient suffering from chronic illness

12) Patient having symptoms of *Grahani*.

C) Withdrawl Criteria –

1) Patients who discontinue the treatment

2) Progressive worsening of disease and development of any complication during the trail.

3) Death of patient due to any cause.

4) Patients not willing to take treatment.

Showing Grouping of Cases -

Group	Group A	Group B
Number of Patients	30	30
Treatment	<i>Amalakyadiloha</i>	<i>Amlapittantakloha</i>
Dose	500 mg BD	500 mg BD
<i>Kalpana</i>	<i>Vati</i>	<i>Vati</i>
<i>Anupan</i>	<i>Sheet Jala</i>	<i>Sheet Jala</i>
Duration	6 Week	6 Week
Time of Administration	<i>Pragbhukta</i> (Before Meal)	<i>Pragbhukta</i> (Before Meal)
Route	Oral	Oral

Selection of Drugs –

Taking the symptoms and *samprati* of *Amlapitta* into consideration “*Amalakyadiloha*” was selected.

***Amalakyadiloha* Content ¹¹**

<i>Amalaki</i>	<i>Lohabhasma</i>
<i>Pipali</i>	<i>Sharkara</i>

Assessment Criteria:-

For assessment of the efficacy of the trial therapy, following parameters were Adopted.

Subjective criteria

1. Avipaka

Grade	<i>Lakshana</i> (symptoms)
G1	Natural appetite for food after 5- 6 hrs of ingestion of mixed Indian food
G2	Appetite for food after 7- 8 hrs of taking food
G3	Appetite for food after 9 – 10 hrs of taking food
G4	Appetite for food after 10 – 12 hrs of taking food

2. Klama

Grade	<i>Lakshana</i> (symptoms)
G1	No tiredness on routine physical work
G2	Feeling tired on routine physical work
G3	Feeling tired to do normal routine work
G4	Feeling tired to do any work or no interest in work

3. Utklesha

Grade	<i>Lakshana</i> (symptoms)
G1	No sensation of vomiting
G2	Nausea 1 – 3 times a week
G3	Nausea 4 – 7 times a week
G4	Frequent feeling of nausea with or without food

4. Chhardi

Grade	<i>Lakshana</i> (symptoms)
G1	No vomiting
G2	Occasional
G3	2-3 times a week
G4	Every day

5. Tiktaamlodgara

Grade	<i>Lakshana</i> (symptoms)
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G1	No regurgitation of gastric content in to the mouth
G2	Rare regurgitation of gastric content in to the mouth
G3	Often regurgitation of undigested food in to the mouth
G4	Frequent regurgitation of gastric content in to the mouth

6.Aruchi

Grade	Lakshana (symptoms)
G1	Having good appetite
G2	Loss of appetite for breakfast and snacks
G3	Loss of appetite for breakfast, lunch, dinner
G4	Aversion of any food

7.Hrit-Kanthdah

Grade	Lakshana (symptoms)
G1	No pyrosis
G2	Pyrosis in empty stomach
G3	Pyrosis in empty stomach as well as after 3-4 hrs of taking meal
G4	Constant or frequent pyrosis

8.Udarashoola

Grade	Lakshana (symptoms)
G1	No pain in the abdomen
G2	Mild pain in the abdomen of low intensity
G3	Moderate pain causing partial interruption in the work
G4	Severe pain complete interruption of work

9. Gaurav

Grade	Lakshana (symptoms)
G1	Absent
G2	Occasional Symptom
G3	Present after meal
G4	Persistent throughout the day

Observation and Results –

According to % relief in symptoms –

Symptoms	Percentage Relief	
	Group A	Group B
Avipaka	62.22%	94.44%

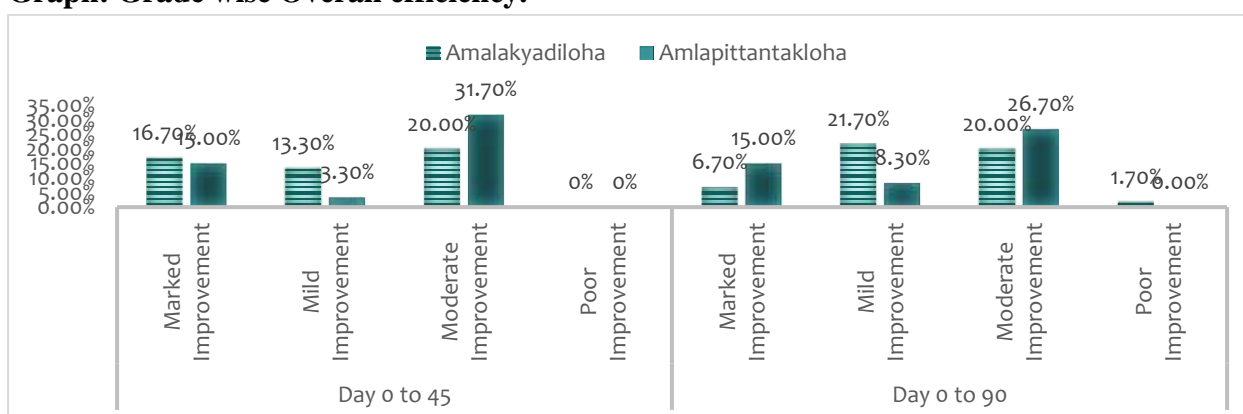
<i>Klama</i>	76.66%	90%
<i>Utklesh</i>	63.88%	80%
<i>Chardi</i>	55%	50%
<i>Tikta amla udgar</i>	61.66%	76.11%
<i>Aruchi</i>	40%	33.33%
<i>Hrutkanthadaha</i>	66.66%	85.55%
<i>Udarshool</i>	33.33%	43.33%
<i>Gaurav</i>	40.55%	48.33%

**Overall Effect of Therapy –
According % Relief –**

Table – Grade wise Overall efficiency

	Day 0 to 45				Day 0 to 90				Total
	Marked Improvement	Mild Improvement	Moderate Improvement	Poor Improvement	Marked Improvement	Mild Improvement	Moderate Improvement	Poor Improvement	
<i>Amalakyadiloha</i>	16.7%	13.30%	20.00%	0%	6.70%	21.70%	20.00%	1.70%	100%
<i>Amlapittantakloha</i>	15%	3.30%	31.70%	0%	15.00%	8.30%	26.70%	0.00%	100%
Total	31.7%	16.6%	51.7%	0%	21.7%	30%	46.7%	1.70%	200%

Graph: Grade wise Overall efficiency.



**Discussion on statistical analysis –
Statistical Analysis: In Trial Group and
In Control Group (By Wilcoxon Signed
Ranks Test)**

Wilcoxon Signed Ranks test was applied to both groups separately and observed whether the difference between before treatment and after treatment score is significant or not. Mean difference of Group A is not much more than mean

difference of Group B and p value is greater than the significance level $\alpha = 0.05$, We should accept the Null Hypothesis (H0) and reject the Alternate Hypothesis H1 & H2. It is hence concluded that, Oral administration of *Amalakyadiloha* is not effective as *Amlapittantakloha* in the management of *Urdhwaga Amlapitta* to reduce *Avipaka, Klama, Utklesha, Chardi, Aruchi, Udarshool, Gaurav* symptoms.

Effect of Therapy According to % Relief in Patients

- **In Group A**, 16.7% (10) patients at day 45 and 6.7% (4) patients at day 90 realized Marked Improvement, 20% (12) patients at day 45 and 20% (13) patients at day 90 realized Moderate improvement, 13.30% (8) patients at day 45 and 21.7% (13) patients at day 90 realized Mild Improvement and 0.00% patients at day 45 and 1.70% (1) patient at day 90 shows Unchanged/Poor improvement.
- **In Group B**, 15% (9) patients at day 45 and 15% (10) patients at day 90 realized Marked Improvement, 31.7% (19) patients at day 45 and 26.7% (15) patients at day 90 realized Moderate improvement and 3.30% (2) patients at day 45 and 8.30% (5) patients at day 90 realized Mild Improvement.

Average % Relief

- Average % Relief was 55.55% at day 45 and 65.7% at day 90 in Group A. Average % Relief was 66.79% at day 45 and 70.12% at day 90 in Group B. Hence According to % relief, It was observed that *Amlapittantakloha* orally with compare to *Amalkyadiloha* orally in the management of *Urdhwaga Amlapitta* is found better on the basis of percentile relief.

Mode of Action –

Amalakyadiloha orally

1) Effect on *Dosha*:-

Amalakyadiloha contains *Amalaki, Pipali, Lohabhasma, Sharkara*. *Amalaki* is *Tridosahar* specially *Pittashamak* as it is *Pancharasatmaka, Madhur Vipaka* and *Sheet Virya*. In *Amlapitta* there is increase *Amla guna* of *Pitta* and *Amalaki* is *Pittashamak*, so it reduces the *Amla guna* of *Pitta* which causes *Amlapitta*.

Pipali is *Kaphavataghna*, it causes *Vatanuloman* and *Mrudu Virechan*. Due to its *Mrudu Virechan* property it decreases vitiated *Pitta dosha* in the body, as *Virechan* is the best treatment for *Pitta dosha*. It helps in reducing the symptoms of *Amlapitta*.

Loha Bhasma is *Tridoshshamak*. *Lohabhasma* is *Ushna, Guru gunatmak, Ushna Virya* and *Madhur Vipaki*. Due to its *Madhur Vipak* it helps in *Pitta shaman* and *Ushna virya* helps in *Deepan, Pachan* and *Agnivardhan*.

Sharkara is *Madhur rasatmak, Madhur vipaki* and *Sheet Viryatmak*. Due to this it is *Vata-Pitta shamak, Dahahar* and increases *Ruchikar* property due to its *Madhur vipaka*.

2) Effect on *Dushya*:-

Amlapitta is a disease in which there is *Rasa dhatu dushti*. Due to this it leads to *Agnimandya, Aruchi*. *Katu ras* of *Pipali churna* and *Tikta ras* and *Ushna virya* of *Lohabhasma* helps to promote the normal *Agni* process, which in turns decreases the symptoms of *Agnimandya*.

3) Effect on *Strotas*:-

Annavaha and *Rasavaha strotas* are involved in this disease. Thus the

content of *Amalakyadiloha* helps in *Aampachan* and proper formation of *Aahar rasa*.

4) Effect on *Vyadhi*:-

Pipali is *Katu rasatmak*, *Ushna*, *Tikshna gunatmak*. Along with *Pipali Ushna Virya* of *Lohabhasma* decreases *Agnimandya* due to its *Deepan*, *Pachan* property and helps to balance *Jatharagini*.

In *Amlapitta Pitta* becomes *vidagdha* due to increase *Amla* and *Drava guna* of *Pitta*. *Amalaki* is *Pitta shamak* so it reduces the *Amla guna* of *Pitta*. Due to *shoshan* property of *Kashay rasa* of *Lohabhasma*, it decreases the *Drava guna* of *Pitta*. Which leads to decreases in symptoms like *Hritkantha daha*, *Amloudgaar*, *Utklesh*.

Shuktapaka of *Anna* causes *Ama* in *Amlapitta* which causes *Annavaha* and *Rasavaha strotas dushti*, in this *Katu ras* of *Pipali* and *Tikta ras* and *Ushna virya* of *Lohabhasma* decreases *Agnimandya* due to its *Deepan*, *Pachan* property and helps to balance the *Jathragini*, Which decreases the symptoms like *Aruchi*.

Conclusion –

Amalakyadiloha and *Amlapittantakloha* both reduced all symptoms significantly. (Wilcoxon Signed Ranks test, $P < 0.05$). Trial Group (*Amalakyadiloha*) average % relief was 66.79% and In Control Group (*Amlapittantakloha*) average % relief was 70.12%.

Finally, We concluded –

Null hypothesis (H0) is accepted i.e. Oral administration of *Amalakyadiloha* is not effective as *Amlapittantakloha* in the management of *Urdhwaga Amlapitta* and **the alternate hypothesis**

(H1) is rejected i.e. Oral administration of *Amalakyadiloha* is more effective than *Amlapittantakloha* in the management of *Urdhwaga Amlapitta*.

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