

## “A CLINICAL STUDY TO EVALUATE THE EFFECTIVENESS OF AN AYURVEDIC INDIGENOUS COMPOUND IN CASES OF URDHWAGA AMLAPITTA w.s.r GERD”

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### ABSTRACT

**Aim:** To evaluate the efficacy of an ayurvedic indigenous compound in cases of urdhwaga amla-pitta. **Introduction:** Amla-pitta is one of the common clinical problems of our day to practice and it is increasing rapidly due to changes in our life style & high level of mental stress. **Settings and Design:** For the present clinical study 50 patients were selected. The patients having Indigestion, Nausea, Retrosternal burning, Anorexia, Acid eructation, Relief by sweet & cold food were selected for present clinical study. **Materials and method:** All patients were divided in two groups -Group-A- 25 patients were kept on yastimadhu ghana satva 800mg and amalki kwath bhavit sankh bhasma 200 mg in form of 2 capsule of 500 mg BD/ day after meal for a period of 6 weeks. Group-B-25 patients were kept on placebo (1000 mg wheat flour) 2 capsule of 500 mg BD/ day after meal for a period of 6 weeks with aahar & vihar (Life style modification). **Type of study:** Phase 2 Rationale Randomized control trial. **Statistical analysis used:** p value, paired 't' test, unpaired 't' test,  $\chi^2$  etc. **Results:** The trial drugs show significant results in terms of cure & improvement in clinical parameters and no any side effect has been observed. **Conclusion:** In cured patients response of treatment in group A is more than group B however group B has good response in improved patients so it's suggested that for urdhwaga amlapitta both drug treatment and life style modification is of great importance.

**Key words:** Yastimadhu, Amalki, Sankh Bhasma, Urdhwaga amlapitta

### INTRODUCTION

In the Ayurvedic system of medicine, a great emphasis has been laid upon the functioning of Agni and Pachak pitta. In the normal state, the agni performs various digestive and metabolic functions. The chain reaction of digestion and metabolism in human body goes well, if the chief agni or the jathragni is within the physiological form. Agni and pitta are closely related, impairment of agni leads to improper digestion leading to various GI disorders. Amlapitta is one of them. It is a very common disease caused by agnimandhya (digestive impairment) and by increased Drava & Amla Guna of Vidagdha Pachaka Pitta affecting the Annavaha Strotas (food conducting channel) and characterized by primary symptoms such as Avipaka (indigestion), Klama (exhaustion without any exertion).<sup>1</sup> This disease affect the human beings due to lack of self awareness of dietary factors along with tremendous increase in the stress and strain in the lifestyle.

In sanhita period Amla pitta is not described as a separate disease but Acharya Charaka has been described the

pathogenesis of Amlapitta in Grahani rog chikitsa.<sup>2</sup> Sushruta while describing the diseases caused by excessive use of Lavana (salt); mentioned a disease "Amlika" which is similar to Amlapitta.<sup>3</sup> Acharya Kashyap was the first to describe Amlapitta or shuktika as separate entity.<sup>4</sup> Later on Madhava Nidana described this disease and its treatment in detail. Two types of Amlapitta namely, Urdhwaga (upward) and Adhoga (downward) on the basis of gati (movement) described by madhavkar.<sup>5</sup> Chakradutta,<sup>6</sup> Bhavaprakasha,<sup>7</sup> Yogaratnakar a,<sup>8</sup> etc., also described this disease with treatment. The classical symptoms of Urdhwaga amlapitta are Avipaka (indigestion), Klama (exhaustion without any exertion), Utklesha (nausea), Tiktaamlaudgar (acidic eructation), Gaurav (heaviness in the body), Hrita kanthadaha (retrosternal burning) and Aruchi (anorexia).<sup>9</sup> Amlapitta is closely similar to GERD in modern medical science, having major symptoms like Heart burn or reterosternal burning, acid eructation, nausea, chest pain and indigesion.

The line of treatment consists of mainly Shodhanakarma (purification), shaman karma (pacifying) and samyak Aahar-vihar (life style modification). We have to choose the most appropriate and effective Shamana (pacifying) therapy and compare it with samyak aahar-vihar (life style modification).

According to Bhavaprakasha, Yasthimadhu is Pittashamaka drug (pacifying Pitta).<sup>10</sup> Due to its Dahashamaka (pacifying burning sensation) and Pittashamaka properties, it can be used effectively in management of Amlapitta. Rasa- tarangini also advocated yasthimadhu and amalkibhavita sankha bhasma in the management of amlapitta.<sup>11</sup>

## MATERIAL AND METHOD

For the present clinical study 54 patients were randomly selected from O.P.D. / I.P.D. department of Kaya-chikitsa State Ayurvedic College & hospital, Lucknow from March 12 to March 13 but 4 patients left the trial in between without prior information. All the patients were randomly divided into 2 groups.

### Inclusion Criteria:

1. Age group: 20 - 60 years
2. Socioeconomic status: All
3. Sex: Both Male & Female

### Subjective criteria:

1. Avipaka (Indigestion)
2. Utklesha (Nausea)
3. Hritkanthdaha (Retrosternal Burning)
4. Arochak (Anorexia)
5. Tikta amlaudgara (Acid eructation)
6. Swadu sheetopshayam (Relief by sweet and cold food)

Each and every symptom was observed in every Patients according to selection criteria and Patients having 75% or more of the following clinical symptomatology were selected for present clinical study.

### Exclusion Criteria:

1. Age group less than 20 and greater than 60 years will be excluded.
2. Ca Stomach
3. Patient with gastrointestinal complications such as peptic ulcer, duodenal ulcer, perforation, stenosis, bleeding, melena, and malignancy
4. Zollinger Ellison Syndrome
5. Patients with other systemic disorders and serious illness
6. Pregnancy and lactating mother
7. Patients of uncontrolled DM and Hypertension.

**Type of Study:** Phase-2, rational, randomized (sequential) control group study

**Period of Study:** Total duration of clinical trial is of 45 days or 6 weeks.

**Follow up Period:** 15 days after treatment

**Grouping and posology:** All the patients registered for the clinical trial were divided into two groups –

**Group-A-** 25 patients were kept on yasthimadhu ghana satva 800mg and amalki kwath bhavita sankha bhasma 200 mg in form of 2 capsule of 500mg BD/ day after meal with fresh water for a period of 6 weeks.

**Group-B-** 25 patients were kept on placebo (1000 mg wheat flour) 2 capsule of 500mg BD/ day after meal with fresh water for a period of 6 weeks with aahar & vihar (Life style modification).

### Criteria of assessment:

The result of treatment was assessed on the basis of improvement in the clinical symptoms with the help of suitable scoring method.

### Criteria for the assessment of overall effect of the therapies:

The total effect of therapy of this trial will be grouped as follows –

**Relieved:** Patients have >75% relief in terms of symptoms, pathological findings in normal range and no recurrence of disease up to follow up period.

**Improved:** Patients having improvement between 40-75% in clinical symptoms and no recurrence of disease up to follow up period.

**Not improved:** Patients having improvement less than 40% in terms of clinical symptoms and recurrence may be occur.

### Statistical analysis:

For statistical analysis Student's paired 't' test was used for assessing the difference between groups. The obtained results were interpreted as non-significant  $p > .05$ , significant  $p < .01$  and highly significant  $p < .001$ . The chi-square test was used for subjective parameters.

Lab investigation:

Routine Investigation:

Blood- TLC, DLC, Hb%, ESR, LFT, KFT

Urine - Routine & Microscopic

Stool - For ova, cyst, & occult blood

Blood sugar: F & PP

Specific Investigation:

1. O.G.D
2. Barium meal X- ray (Stomach Duodenum)

**RESULT**

In the present clinical trial total 54 patients were registered. Out of which 4 were dropout So that the present data are analyzed on the basis of total 50 patients, out of which 25 patients of group A and 25 patients of group B.

**Aetiologial observation:**

In the present clinical study, it was found that the age group of 21-40 years comprises the maximum number of patients 30 (60%).According to sex 21 (42%) patients were male and 29 (58%) patients were female. Maximum number of patients (70%) was Hindu according to religion. Maximum number of patients (24%) was house wife and at 2<sup>nd</sup> unemployed persons (22%). According to marital status maximum number of patients (80%) was married. Maximum number of the patients (60%) belonged to middle class. Maximum number of patients (70%) was non vegetarian. Most of the patients having irregular bowel habit (44%) and constipation (40%).Maximum number of patients (50%) were of disturbed sleep. Maximum number of patients (46%) having blood group O<sup>+ve</sup>. Maximum (48%) were vata-pitta prakriti and (40%) were pitta-kaphaj prakriti. Maximum number of patients (44%) were registered during sharad ritu(Sep-Oct.). Duration of illness was maximum (40%) less than two months.

**Clinical observations:**

All the registered patients were clinically analyzed according textual description. Each and every symptom was observed in each patient. A thorough physical and systemic examination has been done.

It was observed that before use of trial regime most of the patients showed Avipaka (Indigestion) and Hritkantha daha (Retrosternal burning) 100%, Arochak (Anorexia) 90%, Tikta amla udgara (Acid eructation) 82%,Swadu

sheetopshayam (Relief by sweet and cold food) 86% andUtklesh (Nausea)44%.

**Therapeutical observations:**

The drug regimen has shown their effect in almost all the symptomatology.

Avipaka (Indigestion) was present in 25 (100 %) patients in Group-‘A’ and 25 (100 %) in Group-‘B’ cases before the treatment. After treatment 21 patients (86%) in Group-‘A’ and 19 patients (76%) in Group-‘B’ were relieved. 4 patients in Group-‘A’ and 5 patients in Group-‘B’ were improved. Hritkantha daha (Retrosternal burning) was present in 25(100 %) cases in Group-‘A’ and 25 (100%) cases in Group-‘B’ before the treatment. After treatment20 patients (80%) in Group-‘A’ and 20 patients (80%) in Group-‘B’ were relieved. 4 patients in Group-‘A’ and 3 patients in Group-‘B’ were improved. Arochak (Anorexia) was present in 22 (88%) cases in Group-‘A’ and 21(84%) cases in Group-‘B’ before the treatment. After treatment 18 (81.80%) patients in Group-‘A’ and 18 (78.3%) patients in Group-‘B’ were relieved. 4 patients in Group-‘A’ and 3 patients in Group-‘B’ were improved. Tikta-amlu udgara (Acid eructation) was present in 20 (80%) cases in Group-‘A’ and 21 (84%) cases in Group-‘B’ before the treatment. After treatment 18 (90%) patients in Group-‘A’ and 19 (90 %) patients in Group-‘B’ were relieved. 2 patients in Group-‘A’ and 1 patients in Group-‘B’was improved. Swadu sheetopshayam (Relief by sweet and cold food)was present in 22 (88%) cases in Group-‘A’ 21 (84%) cases in Group-‘B’ before the treatment. After treatment 19 (86.4%) patients in Group-‘A’ and 19 (90.5 %) patients in Group-‘B’ were relieved. 2 patients in Group-‘A’ and 1 patients in Group-‘B’was improved. Utklesh (Nausea) was present in 10 (40%) cases in Group-‘A’ 12 (48%) cases in Group-‘B’ before the treatment. After treatment 10 (100%) patients in Group-‘A’ and 11(91.7 %) patients in Group-‘B’ were relieved. The Comparative study of the Symptomatology as well as the pathological investigation were performed before and after treatment provided following results-

**Table 1: Showing the results in percentage after treatment**

S. No.	Group	Arogya (Relieved)		Kinchit Arogya (improved)		Anarogya (not improved)	
		No. of patients	% Age	No. of patients	% Age	No. of patients	% Age
1.	‘A’ (Sanshman)	18	72%	6	24%	1	4%
2.	‘B’ (Life style modification)	15	60%	7	28%	3	12%

During the trial of treatment no any side effect has been observed.

It was clearly observed that this symptom was relieved in both the Group 'A' and 'B'. Statistical data shows that significantly improvement ( $P < 0.001$ ) in symptoms in both groups but not statically significant intergroup comparison.

**Table 2: "Significance of treatment on different signs and symptoms"**

S. No.	Name of Symptoms	Statistical Assessment					
		Group 'A'			Group 'B'		
		% response	$\chi^2$	P value	% response	$\chi^2$	P value
1.	Avipaka (Indigestion)	84%	44.2	$P < 0.001$ Significant	76%	35.6	$P < 0.001$ Significant
2.	Utklesha(Nausea)	90%	11.8	$P < 0.01$ Significant	91.7%	13.8	$P < 0.01$ Significant
3.	Hritkanthdaha (Retrosternal Burning)	80%	36.4	$P < 0.001$ Significant	80%	34.4	$P < 0.001$ Significant
4.	Arochak (Anorexia)	81.8%	35.2	$P < 0.001$ Significant	78.3%	36.9	$P < 0.001$ Significant
5.	Tikta-amlaudgara (Acid eructation)	90%	29.4	$P < 0.001$ Significant	90%	30.6	$P < 0.001$ Significant
6.	Swadu sheetopshayam (Relief by sweet and cold food)	86.4%	31.0	$P < 0.001$ Significant	90.5%	29.9	$P < 0.001$ Significant

So the trial treatment shows significant results in terms of improvement in clinical parameters.

**Table 3:**

S.No.	Clinical features of Urdhwaga Amlapitta	Clinical features of GERD
1.	Avipaka	-
2.	Tikta amla udgara	Acid eructation
3.	Hritkanthdaha	Heart burn or Retrosternal burning
4.	Utklesh	Nausea
5.	Kukshi daha	-
6.	Swadusheetopayam	Relief by cold and alkalies
7.	Klama	Feeling of restlessness

## DISCUSSION

Amlapitta is a disease of Annavaha srotas (GIT). Amlapitta means amlibhoot pitta due to amlarasa, continuous and sustained increase vidagdha pitta (more acidic pitta) in the amashaya is considered to be the root cause of amlapitta. In modern system of medicines two terms Non

ulcer dyspepsia and reflux esophagitis has been described due to malfunctioning of gastrointestinal tract<sup>12</sup>. GERD shows more resemblance with disease Urdhwaga Amlapitta as shown below in table no. 3–

The management of Urdhwaga amlapitta is completely based on the samprapti vighatan i.e. correction of state of

Agnimandhya, elimination of shuktatva resulting due to pitta dushti, evacuation of dushta pitta resulting srotoshodhan and anuloman of apana vayu. The present clinical trial consists of yastimadhu Ghana satva and amalki kwath bhavit sankh bhasma because Amlapitta is essentially produced by the imbalance of pitta and kaphadosha. Kashaya rasa and sheeta veerya aushadhi is corrective for both of them.

Yashtimadhu is having Madhura Rasa, Guru & snigdha Guna, Sheeta veerya and Madhura vipaka, it is Pitta-Vata Shamaka and is Dahaprashamaka, Balya (tonics), Glani (depression of mind), and Kshayahara (relieving wasting disorders).<sup>13</sup>

Madhura Rasa and Sheeta Veerya of Yashtimadhu acts by decreasing the vitiation of Pitta Dosha. Urdhwaga Amlapitta is a Pitta pradhan vyadhi, where some association of Vata and kapha can also be traced. Yashtimadhu is having Pitta-Vatashamaka property, and could work in Samprapti Vighatana (breakdown in the pathogenesis) of Amlapitta.

Amalki is Tridoshar specially pittahara Dahaprashmana, Rochan, Deepan, Amlata nashak and anuloman.<sup>14</sup>

It suppresses to vata by amlarasa, to pitta by madhur rasa and sheeta guna, to kapha by rukshaguna and kashaya rasa. It also acts as laxative, so it is widely used in paittika disorder like urdhwaga amlapitta because virechana is best treatment for paittika disorder. It also corrects the aruchi and agnimandhya and predominantly used in paittika disorder.

Sankh bhasma having the properties of Katu rasa, Laghu-Ruksha guna, Katu vipaka, Sheeta veerya and Kshareeya in nature. This is deepan, Pachan, Amlata nashak and kaphagna.<sup>15</sup> Calcium carbonate, Phosphate and magnesium which is present in Sankh bhasma which act as Antacids.

The synergistic action of both the drugs act against the basic cause of the disease amlapitta i.e. Agnimandhya, Pratiloma gati of apana vayu and loss of mucosal protective action of kledak kapha. The malfunctioning of Pachak pitta and Agni corrected by its deepan, pachan and rochan guna karma of amalki and sankh bhasma. The mucosal protective action preserved by yastimadhu and anuloman of vayu by amalki. The action of drug is slow but steady.

## CONCLUSION

On the basis of present clinical trial following conclusion have been drawn-

- Urdhwaga amlapitta is a disease of gastrointestinal tract and is produced by vitiation of pitta dosha due to Agnimandhya, Pratiloma gati of apana vayu and loss of mucosal protective action of kledak kapha.
- According to etiology, pathogenesis, clinical manifestations and treatment of Urdhwaga Amlapitta is almost similar to that of Non ulcer dyspepsia & GERD of modern medicine.
- The disease is more prevalent in age group 21-40 yrs, in females, vata-pittaj prakriti with blood group 'O'.
- Tea-coffee, Tobacco, Panmasala, Smoking, Spicy food, mental stress, anxiety and disturbed sleep are precipitating factors in its causation.
- The regimen was given to the selected patients were well accepted & tolerated with good positive response. Statistically the result was highly significant in both group however intergroup comparison is not statistically significant but the response was higher in Group 'A' than Group 'B'.
- So it's suggested that for urdhwaga amlapitta both drug treatment and life style modification is of great importance. Thus the regimen may prove a valuable contribution from Ayurveda towards the ailing humanity.

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