

EFFICACY OF CHATUHSAMA IN AMLAPITTA W.S.R. TO HYPERCHLORHYDRIA

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ABSTRACT

Hyperacidity or acid dyspepsia (*Amlapitta*) is a very common disorder which affects almost 30% people in India as well as European countries each year. It occurs due to irregular and tiresome lifestyle. The management of this disease is somewhat difficult and patients are continuously looking with a hope towards Ayurveda to overcome this challenge. Chatuhsama is an Ayurvedic drug which pacifies vitiated *Pitta* by their properties. Chatuhsama is made up of ingredients like *Amalaki* (*Phyllanthus emblica*) Sita (Crystalline sugar), *Shatavari* (*Asparagus racemosus*) and *Madhu* (Honey) in equal quantities. These

drugs possess the *Pittahar* properties which help in treating *Amlapitta*. Present research work was planned to evaluate efficacy of *Chatuhsama* in the management of *Amlapitta*. 60 patients were randomly selected and divided in two groups. In experimental group A, *Chatuhsama* with cold milk is given twice day in the form of *Lehya* whereas in control group B, placebo treatment is given. It is observed that *Amlapitta* is seen in middle age irrespective of sex. It is usually seen in those whose lifestyle is not fixed and consumes spicy, oily food mostly. *Chatuhsama* is effective in *Rasavaha* and *Annavaha strotas*. It can be an ideal treatment for all stages of *Amlapitta* due to its efficacy and the results which were found significant statistically in the study.

KEYWORDS: Chatuhsama, Amlapitta.

INTRODUCTION

Hyperacidity or acid dyspepsia (*Amlapitta*) is a very common disorder which affects almost 30% people in India as well as European countries each year. Hyperacidity could be described as a disorder of the modern and urban cities, where the eating habits of people are quite irregular. Hyperacidity (*Amlapitta*) simply means increase of acidity in the stomach.

Normally Hydrochloric acid (HCl) secretes in the stomach of human body for the digestion of food, while its secretion has excess amount the condition is called as hyperacidity or acid dyspepsia.^[1]

In *Samhitas*, *Amlapitta* is not mentioned as a separate disease entity but there are several references in *Charaka Samhita* regarding *Amlapitta*. *Madhavakara* and *Kashyapa* have described this disease as a separate entity with detailed description. *Kashyapa*^[2] has accepted the involvement of three *Doshas* in *Amlapitta* while *Madhavakara*^[3] has accepted the dominance of *Pitta* in this disease. This disorder is the result of *Grahani Dosha* (Duodenal disease). *Charaka* and *Kashyapa* have clearly indicated that the *Grahani Dosha* and *Amlapitta* occur in the persons who fail to check the temptation of food. *Ajirna* (Indigestion) after encountering the specific *Doshas* and affinity with specific site may cause various diseases.^[4,5,6] Gastritis and non-ulcer dyspepsia have been correlated with *Amlapitta*. Patients of gastritis often result into peptic ulcer. Purificatory therapy procedure has given importance in this disease by *Sangraha Granthakara*. But it is opted less frequently in practice due to more time consumption and today's tiresome lifestyle. *Acharyas* have mentioned usage of the drugs which are having *Tikta Madhura Rasa*, *Madhura Vipaka*, *Sheeta Virya* and *Laghu*, *Ruksha* property with *Kapha pittahara* action for the same. In modern science it is managed with antacids, anti-ulcers and anti-secretory drugs, being *Ranitidine* the most favorite and nowadays second generation drugs like *omeprazole*, *H2* blockers can successfully control gastric irritation but these drugs are having several ill effects like skin rash, headache, constipation.^[7,8,9] There are innumerable herbal and herbo-mineral preparations available in market for *Amlapitta*. But effective drugs have not yet been developed properly for the complete cure of the disease. Also the modern medicines have many types of complications in this regard. Usually most of the cases treated with different formulations have the chances of recurrences and also patients may become addicted to such medicine. In *Ayurveda* classic *Chatuhsama* is mentioned in *Vangsen Samhita* which is best indicated in *Amlapitta*. Thus considering the above factors in present scenario the clinical study was conducted to evaluate the anti-secretory effect of *Chatuhsama* which is easily consumable as it is in *Lehya* form.

AIMS AND OBJECTIVES

The main aim of the present study is to assess the anti-secretory action of *Chatuhsama* in *Amlapitta*.

Preparation of Trial Drug^[10] The author *Vangasen* of *Vangasen Samhita* has explained the *Chatuhsama* under *Amlapitta prakarana* to treat *Amlapitta*. The formulation consists of Sita (Crystalline sugar), Amalaki, Shatavari and honey in equal quantities. It should be consumed with *anupana* milk.

METHODOLOGY

CLINICAL STUDY For the Clinical study *Chatuhsama* is administered empty stomach with milk as *Anupana* (vehicle) considering its effect on the GIT diseases.

Selection of patients:-

Method of collection of data

Present study is a prospective clinical study. The patients with *Amlapitta* w.s.r.to Hyperchlorhydria within the age group of 15 yrs to 60 yrs were selected randomly from O.P.D of MGACHRC after fulfilling the inclusion and exclusion criteria irrespective of their sex, occupation and socio-economic status.

Sample size A minimum of 30 patients were taken including the dropouts. The present study is a double group study where in patients were assigned in two groups. It is a simple random sampling technique clinical trial with one placebo group.

A quick sneak into the pathology of the disease in GIT gives brief information that on an average 500 ml of gastric juice is secreted per meal in the stomach which is acidic in reaction. Gastric acid hyper secretion occurs in Zollinger Ellison's Syndrome, Peptic ulcer, G-cell hyperplasia etc. The chronic acid hyper secretion may lead to several other complications, so it is essential to prevent it in prior stage only. In Excessive intake of oily, spicy and salty foods; excessive intake of sour foods that contain high acid content, inadequate exercise; go to bed immediately after a heavy meal, too much mental stress and worries; consumption of alcohol, smoking and drug addiction and too much intake of therapeutic allopathic medicines are triggers of hyperacidity (*Amlapitta*). There is a mention of *Amlapitta* since the *samhita* period. *Kulattha* (*Dolichus biflorus*), *lavana rasa*, *viruddha ahara* etc. are described as the causative factors for *Amlapitta*.^[2]

Sushruta samhita describes condition of *Amlika* similar to *Amlapitta* because of excessive intake of *Lavana rasa*.^[3] *Kashyapa samhita* is the first available text which explained *Amlapitta* as separate entity.^[4] *Madhava nidana* described two types of *Amlapitta* namely,

Urddhvaga and *Adhoga*^[5] *Chakradutta*,^[6] *Bhavaprakasa*^[7], *Yogratnakara* etc. also described of this diseases with treatment modalities. The burning sensation in upper abdomen/chest, acid eructation, water brash, nausea, vomiting, vertigo and flatulence characterize it 9. The treatment of this disease in allopathic medicine depends upon mainly on antacids and tranquilizers. The management of the disease in *Ayurveda* is based on *shodhana* and *shamana* chikitsa. A number of herband herbomineral drugs are mentioned for its management. The medical management of this disease condition/clinical problem in prevalent system of medicine still requires further improvement. Therefore, it is considered worthwhile to assess clinical efficacy of classical *Ayurvedic* preparation like *Avipattikar churna* and *Kapardika bhasma* due to their antacid properties (*Amlapittashamak*) described in literature. A clinical study was conducted at central research institute for Ayurveda, poddar hospital campus, Mumbai to evaluate the efficacy of the drug. The aims and objectives are to assess the efficacy of classical *Ayurvedic* formulations on *Amlapitta* (hyperacidity) and to establish an integrated approach of *Ayurveda*.

MATERIAL AND METHODS

An open, comparative randomized clinical study was conducted at OPD level of Mahatma Gandhi Ayurved College Hospital & Research Salod (H), Wardha. The study protocol, case record forms (CRFs), regulatory clearance documents, product related information and informed consent forms were submitted to the Institutional ethics committee (IEC) and were approved by the same.

Criteria for the selection

Exclusion criteria

Following were the criteria to exclude the patients from the study:

1. Patient below 15 and above 60 years of the age.
2. Patients with complications like Peptic ulcers, Acute or Chronic Gastritis, any secondary infections or syndromes and Medical Emergencies.
3. Pregnant women and lactating mother.
4. Any other systemic disorders other than *Amlapitta*.
5. *Amlapitta* patients along with metabolic diseases, such as Diabetes and Hypertension.
6. Complication which intervenes the course of treatment.
7. Patients on chemo and radio therapy for malignancy, chronic hypertrophy gastritis, patient suffering from any chronic systemic diseases and diseases of Liver and Kidneys.

8. Colic pain in abdomen pertaining to any organic lesion.

Inclusion criteria: The selection of the patient for clinical study was done with following criteria.

1. Age of patients between 15 to 60 years
2. No discriminations of chronicity and severity of disease
3. Patients of classical *Amlapitta* symptoms irrespective of gender, caste, occupation and economic status.
4. *Amlapitta* of any *Dosha anubandha* (associated *Doshas*).
5. Cases of *Amlapitta* in whom treatment was interrupted are considered with a period of one week gap and then selected for treatment.
6. Who have clinical sign and symptoms of Hyperacidity (*Amlapitta*) like burning sensation in upper abdomen, burning sensation in chest, acid eructation, water brash, nausea, vomiting, vertigo were selected for this study.

Criteria of Diagnosis

Diagnosis is made on the basis of classical symptoms and presence of prominent feature of *Amlapitta*.

Study design: Clinical observational study Simple random sampling techniques. **Posology:** *Chatuhsama*^[10] started with 2 gm twice in a day, empty stomach for 28 days with cold milk as *Anupana*. **Study duration:** 28 days study **Follow up:** After every 7 days. **Criteria for Assessment:** The symptoms as per the classical norms and the investigations as per the modern norms are both considered subjective and objective parameters. They are mentioned in the table 1.1 below.

Table 1: Showing the Various Criterion for Assessment of *Amlapitta*

paired 't' test and S.D., S.E. and P value were calculated.

The symptoms of *Amlapitta* in classical text are as follows: -^[11, 12]

Avipaka (Indigestion)

Klama (Tiredness)

Utklesh (Nausea)

Tiktamlodgar (Bitter Eructations)

Gourav (Heaviness in body)

Hritkanthadaha (Burning sensation in throat)

Aruchi (Tastelessness).

GRADING CRITERIA Table 1: showing the grading criteria of the assessment parameters

Table No. 1:- Scoring pattern adopted to assess the symptoms of the diseases is as follows:-

Sign & Symptoms	Grading				
	0	1	2	3	4
Avipaka (Indigestion)	No indigestion	Mild indigestion causing no disturbance in day to day activity	Moderate indigestion	Severe indigestion causing disturbance in day to day activity	Severe indigestion disturbance in routine activity with occasional diarrhoea
Klama (Mental Fatigue)	No complaint	Mild depression with occasional headache	Moderate depression with stressful condition	Severe stress with heaviness in head & headache, relieved by vomiting	Continuous heaviness in head and headache not relieved by vomiting.
Utklesh (Nausea)	Absent	Occasional desire to vomit	Frequent desire to vomit	Regular desire to vomit	Regular desire to vomit with profuse water brash
Tiktamlodgar (Bitter & acidic eructation)	Absent	Occasional complaint	2 or 3 times a day	Frequently	Regular complaint
Gourav (Heaviness in the body)	No complaint	Mild heaviness in the body	Moderate heaviness in the body	Severe heaviness in the body	Very severe heaviness in the body
Hritkanthadaha (Retrosternal Burning)	Absent	Occasional complaint of warmth sensation in substernal area subsides itself	Warmth sensation in substernal area, 1-2 times per day gets relieved by food and water	Frequent feeling of warmth or burning sensation substernally, gets relieved by taking medicine	Continuous feeling of warmth or burning sensation substernally, does not relieved by taking medicine
Aruchi (Loss of appetite)	Normal appetite	Mild loss of appetite	Moderate loss of appetite	Severe loss of appetite	Very poor appetite

Patients were assessed before and after the treatment for improvement in symptoms on the basis of above said scoring pattern and percentage of improvement were calculated.

Final Assessment of Results

Cured – 100 % relief in symptomatology

Marked improvement – 76 – 99% improvement in symptoms

Moderately improved – 51 – 75% improvement in symptoms

Mildly improved – 26 – 50% improvement in symptoms

Unchanged – Below 25% improvement in symptoms

CLINICAL STUDY**Method of collection of data****PARAMETERS****PLACE OF STUDY**

Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H), Wardha.

Study Design – Prospective and Analytical**Sample size and grouping**

A random sample of 30 each in 2 groups in which one is study group of *Chatuhsama* and second of placebo control group.

Evaluation and Assessment

- The data was collected from all patients who were suffering from *Amlapitta*.
- **Investigations** – Hb%

OBSERVATION AND RESULTS

It has been observed that the age group in which *Amlapitta* mostly occurs is in middle age i.e. during 31- 40 yrs age. In this study it was observed in 20 (40%) patients out of 60 and the cause is overwork, stress, irregular daily regimen and incompatible diet. Depending upon sex, it was observed that it was more in females (62%) than in males (36%). It is observed that 24 housewives (48%) out of 60 patients and 10 farmers (20%) were suffering from the disease due to habit of day sleeping, more sitting at one place and suppression of voluntary physiological urges. Farmers come in contact with cold weather, cold water which is the can be considered as one of the causes of the disease. Depending upon diet, 37 patients (74%) were of mixed diet pattern and 13 patients (26%) were of vegetarian. The disease mainly occurs due to consumption of meat which is heavy to digest and may creates incompletely digested toxic materials in body fluids i.e. Depending upon economical status, 26 patients (52%) belonging to middle income group and 24 patients were of low income group. Due to low economic condition in studied samples, there may be lack of proper body nourishing diet which resulted deficiency of essential body constitutes and such condition leads to aggravation of and thereby production of. 17 patients (34%) of were found suffering from which indicates these are more prone to this disease. According to data related to (digestive capacity), 25 patients (50%) (irregular digestion) and 16 (32%) of (low digestive ability) were found due to vitiation of were found. Depending upon body posture which is related to proper

diet and nourishment, 39 patients (78%) have medium posture whereas 4 (8%) were obese and 7 (14%) were of slim-bodied. Depending upon (strength of visceral organs specially stomach and intestine), 22 patients (44%) were of (hyperactive) whereas 16 patients (32%) were of (low functioning) This prediction suggests that (indigestion) is one of the causes for this disease. Depending upon literacy rate, 37 (74 %) were found literate who perform overwork, having irregular diet; lack of exercise and have stress load which are responsible factors for triggering the possibility of manifestation of this disease.

Hematological Investigations

Blood investigation Hb% was carried out for assessment and it was observed that in group A, out of 30 patients, 15 females and 15 males were investigated for Hb% test in which mean Hb% of males was observed 10.9 gm% before treatment and 11.4gm % after treatment. In females also Hb% was observed as 9.9 gm% before treatment and 10.6 gm % after treatment. In group B, out of 30 patients, 14 females and 16 males were investigated in which mean Hb% of males was observed as 10.9 gm% before treatment and 10.9 gm % after treatment. In females also Hb% was observed as 10.8 gm% before treatment and 10.8 gm% after treatment. Thus out of 60 patients mean Hb% was observed as mean 10.9 gm% before treatment and increased up to mean 11.1 gm% in males whereas in females it was mean 10.3 gm% before treatment and increased up to mean 10.7 gm%. As described in Ayurved literature that the *Pitta* is the Mala of Rakta and if the vitiated *Pitta* gets purified by the drug then blood is formed properly so it was seen in increased percentage of haemoglobin after the administration of Chatuhsama.

Table No.2:- Chatuhsama group.

Sr. No	Symptom	BT	AT	Mean diff.	% change	SD	SEM	t	p value
1.	Avipaka	1.733	0.433	1.300	75.01	0.837	0.153	8.510	=<0.001
2.	Klama	0.633	0.000	0.633	100	0.490	0.0895	7.077	=<0.001
3.	Utklesh	0.933	0.0333	0.900	96.43	0.803	0.147	6.139	=<0.001
4.	Tiktamlodgar	1.367	0.200	1.167	85.37	0.791	0.145	8.074	=<0.001
5.	Gourav	0.700	0.000	0.700	100	0.535	0.0977	7.167	=<0.001
6.	Hritkanthadaha	2.000	0.400	1.600	80	0.724	0.132	12.105	=<0.001
7.	Aruchi	0.533	0.000	0.533	100	0.507	0.0926	5.757	=<0.001

Table No. 3:- Placebo group.

Sr. No.	Symptom	BT	AT	Mean diff.	% change	SD	SEM	t	p value
1	Avipaka	2.000	1.433	0.567	28.35	0.568	0.104	5.461	<0.001
2	Klama	1.200	0.833	0.367	30.58	0.490	0.0895	4.097	<0.001
3	Utklesh	1.600	1.133	0.467	29.19	0.507	0.0926	5.037	<0.001
4	Tiktamlodgar	1.567	1.367	0.200	12.76	0.407	0.0743	2.693	= 0.012
5	Gourav	1.033	0.767	0.267	25.75	0.450	0.0821	3.247	=0.003
6	Hritkanthadaha	1.700	1.333	0.367	21.59	0.490	0.0895	4.097	=<0.001
7	Aruchi	1.333	1.100	0.233	17.48	0.430	0.0785	2.971	=0.006

Table No. 4:- Comparative analysis of Chatuhsama and Placebo group.

Sr. No.	Symptom	% Relief		Diff in %	X2-value	p value
		Gr. I	Gr. II			
1	Avipaka	75.01%	28.35%	46.66%	44.22	0.0001,S
2	Klama	100%	30.58%	69.42%	105.30	0.0001,S
3	Utklesh	96.43%	29.19%	67.24%	95.77	0.0001,S
4	Tiktamlodgar	85.37%	12.76%	72.61%	103.7	0.0001,S
5	Gourav	100%	25.75%	74.25%	117.50	0.0001,S
6	Hritkanthadaha	80%	21.59%	58.41%	67.31	0.0001,S
7	Aruchi	100	17.48%	82.52%	141.9	0.0001,S

DISCUSSION

Statistical point of view: 17.62% patients showed marked improvement, 52.92% patients showed moderate improvement while 29.9% showed slight improvement and no patient remains unchanged.

Drug action point of view: *Amalaki* is having Anti -ulcer, cyto- protective and Anti secretory proper-ties and causes decrease in pyloric –ligation induced basal gastric secretion. Dopamine released within the walls of the stomach as an endogenous neurotransmitter is known to impede gastric emptying.^{[13],[14]} The dried root of *Shatavari (Asparagus racemosus)* is used in Ayurveda for both relief of amlapitta and shoola (dyspepsia). *Sita* is a refined product of sugarcane. It is highly purified. It has cooling properties and due to this property it helps decreasing acidity, and heartburns etc.^[15] Light and easily digestible foods like old *Sali* (rice / *Oryza sativa*), *Yava* (Barley/*Hordeum vulgare*), wheat, *Mudga* (green gram), meat, meat soups, honey etc. are considered wholesome in hyperacidity.^[16]

The contents of *Chatuhsama* are *Laghu* and *Ruksha* in property. There is increase of *Drava Guna* in *Amlapitta*. *Kledaka Kapha* and *Pachaka Pitta* are *Drava* in dominancy. So *Laghu-Ruksha Guna* performs the function of *Dravansha - Shoshana*. Other functions of *Laghu*,

Ruksha Guna are *Lekhana*, *Stambhana* and *Ropana*. This formulation is *Tikta* dominant and it performs the functions of *Pachana* rather than *Deepana*. *Tikta Rasa* helps in *Shoshana* of *Jala* dominant substances which includes *Kleda*, *Meda*, *Vasa*, *Lasika*, *Pitta* and *Kapha*. *Tikta-Kashaya Rasa* helps in pacifying the *Kapha-pitta* both. In these two *rasa Tikta* is better as it is *Laghu* and it does not stagnate the *Ama*. It performs the function of *Pitta-Sleshma Shoshana* as described by *Charaka*. “*Tikta Vishadyati*” can be observed throughout gastrointestinal tract (G.I.T.).^[17,18,19]

All contents of this formulation balance the each others drawback. As *Tikta* is *Avrishya* and *Vatakaraka* but are opposite to it. *Ksheera* also plays an important role as it is *Pathya* for *Amlapitta*

CONCLUSION

Amlapitta a foremost disease can be understood as the normal functioning of the *Agni*, *Pachaka pitta* (the secreto enzymatic functioning of GIT) where diet plays a vital role. It is chronic in nature.

The drug under trial *Chatuhsama* was effective in hyperacidity condition. It relieved hyperacidity in 9 patients remarkably, 14 moderately & 7 patients ended with improving well.

It was observed that patients taking *Chatuhsama* were relieved of their symptoms after 15 - 28 days drug regimen. It was observed that the drug is specifically effective in all cases of *Amlapitta*. This beneficial effect of trial drug may be due to *Tikta Rasa*, *Laghu - Ruksha* property and *Kapha pittahara* action of the combined drug of this preparation.

Chatuhsama exhibited specific role in relieving the cardinal signs & symptoms of *Amlapitta*. These findings have proved that *Chatuhsama* has got specific therapeutic activity in the treatment of *Amlapitta*. Ingredients of *Chatuhsama* are easily available and it can be also used as home remedy for *Amlapitta*. This study has shown that the signs and symptoms of *Amlapitta* are cured by this formulation in small sample but more research should be carried out on large sample.

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