

CLINICAL EVALUATION OF ELADI CHURNA IN THE MANAGEMENT OF "AMLAPITTA ROGA" W.S.R. TO "GASTRO ESOPHAGEAL REFLUX DISEASE (GERD)"

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ABSTRACT

AMLAPITTA is the *Pitta* dominant disease of *Annavaha srotasa* with multifactorial clinical signs and symptoms. Till now, modern medical science has not ruled out permanent curative medicine for this disease. So, research work of this disease is going on by many medical experts and research scholars and they have been succeeded partially in controlling it. Taking this into consideration about *Amlapitta* the present study entitled - Clinical Evaluation Of *Eladi Churna* In The Management Of *Amlapitta Roga* W.S.R To "Gastro Esophageal Reflux Disease" (GERD), has been carried out to establish the efficacy of the treatment .For the present clinical study,30 patients were selected randomly from IPD and OPD of our hospital irrespective of Religion.Sex,Occupation and socio-economic status showed sign and symptoms of *Amlapitta* .The *Eladi churna* 3gm was given orally two times in a day in *Purvabhakta kala* .The followup was recorded after every week.The observations obtained are analysed statically.For obtaining results Student Paired T test is used.The results showed that *Eladi churna* is significant in the management of *Amlapitta*.

Keywords: *Amlapitta, Eladi churna, GERD, Ayurveda.*

INTRODUCTION

Ayurveda is an ancient system of medicine known to mankind for more than 5000 years. "*Ayu*" means Life and "*Veda*" means Science .Thus *Ayurveda* is an immortal science of life that deals with all the aspects of life. It covers all the spheres of human life. It is not merely a materialistic science, but a philosophical and faithful truth which our great ancestral sages, through their experience, logic and power of wisdom. *Ayurveda* has been responsible for "*Svasthanya Svasthya Rakshanam*" and "*Aaturasya VikaraPrashamanam ch*"

which means to maintain the positive health of a person, the next objective being the cure of manifested disease. According to *Ayurveda*, one should not be only free from physical ailment, but also should be mentally happy and spiritually elevated^{1,2}.

The period of 21st century is regarded as the era of fast technology and of high competition, due to which man is subjected to major events of stress and strain. Stress and busy schedule has become their favourite excuse for engulfing fast food, Mcdonald, Pizza hut or road side food. No wonder there

are thousands who suffer from nutritional deficiency diseases but there are other food related diseases among this high class population also. People who do not eat healthy will have dozen of health problems especially related to GIT which are much more bothering than the infective diseases. The altered life style activities like fried food, spicy food, heavy food, alcohol, Night shifts, mental stress, addiction etc, are the major risk factors for *Amlapitta*. Today's life style has completely changed it is not suitable for the normal physiology of digestion in body. 25 ~ 30 % peoples are suffering from GERD, dyspepsia which often results into peptic ulcer. Excessive consumption of *Pitta prakopaka Ahara, Vihara* leads to *Amlata, Dravata, Vriddhi* of *Pitta* causing *Shuktata* of *Pitta* and manifestation of the disease *Amlapitta*.

The word *Amlapitta* is made up of two words *Amla + Pitta* i.e. *Amlapitta*. *Amla* literally means sour, citrus or acidic. "***Amlam vidagdham cha tatt Pittam Amlapitam.***" *Pitta* when gets *Vidagdha* becomes sour in taste leads to *Amlapitta*. "***Amlapitam ceti amla gunodriktam pittam.***" means when *Amlata* (sourness) of *pitta* is increased it leads to *Amlapitta*. In the pathogenesis of *Amlapitta*, there is an increase in the *Amla Guna* of *Pachak Pitta* and this *Amlibhoot Pitta* does not perform its digestive function. All digestion is dependent on the proper functioning of *Agni* and vitiation of *Agni* is the main pathophysiological derangement in this disease. Due to derangement of functions of *Agni*, a metabolic disequilibrium is produced leading to production of *Ama*. Therefore what so ever food is taken remains undigested and gets fermented to

Shukta form and is manifested in the form of *Amlapitta*^{3,4}.

The person with pre-existing tendency of excessive *Pitta* secretion when habitually takes incompatible food like *Virudha Aahara*, excessive intake of *Kulatha & Madya*, living in *Aanoop desha, Sharad* and *Varsha Ritu*, having unhygienic, excessively sour food, produces heartburn leading to vitiation of *Pitta* & its mal - secretion. This condition is called *Amlapitta*. According to *Ayurveda, Mandagni* (reduced digestive fire) is the mother of all diseases including *Amlapitta*. The excessive use of analgesics esp. NSAID's, smoking, alcoholism, hot drinks, spicy food and tobacco lead to the gastric complaints like heartburn, nausea and vomiting. These gastric complaints mimic the symptoms of *Amlapitta*. The disease entity described under the heading of *Amlapitta*, has constellation of symptoms like heart burn, abdominal pain, sour belching, reflexes of food taken, nausea and loss of appetite etc⁵.

The term "*Amlapitta*" can be co - related with "Gastro Esophageal Reflux disease", "Gastro Esophageal Reflux Disease" is define as Reflux of gastric contents into the esophagus resulting in inflammation of esophagus (reflux esophagitis) caused by H⁺ ions, Pepsin and bile salt.". Fatty meal, Hiatus hernia, prolonged gastric tube intubation; Ascitis, Obesity, Alcohol and Smoking are considered as the causative factors of GERD.

Sign and Symptoms of GERD are:-
Typical symptoms:-Heart and Acid Regurgitation. Atypical symptoms:-Dysphagia, Non-Cardiac chest pain & dyspepsia. Extra esophageal:-Hoarseness, Sorethroat & Dental erosions symptoms. GERD commonly

occurs as a chronic digestive disorder affecting 30-40% of general population. GERD is a very common condition with a high prevalence throughout the world, adversely affecting the quality of life of patients⁶. The conventional remedies being used by the modern science have many adverse effects. A good number of research works have been carried out on *Amlapitta* and many of the clinical trials have proved effective to some extent but failed to provide satisfactory answers to all associated problems. Keeping all these factors into effective consideration, a clinical study was planned. In *Ayurveda*, several herbs and formulations have been tried on various aspects of *Amlapitta* as the herbal drugs have been known to provide a new therapeutic approach in the management of *Amlapitta*. For this research study, "*Eladi Churna*" has been selected the management of *Amlapitta*. The present study is purely clinical and was under taken in the

OPD of 30 patients. The present study entitled "**Clinical Evaluation of *Eladi Churna* in the Management of *Amlapitta Roga* w.s.r to Gastro Esophageal Reflux Disease (GERD)**". The study highlights both conceptual and clinical aspects related to the disease *Amlapitta*.

AIM: 1 Conceptual and Clinical study of *Amlapitta* vis-a-vis GERD

2. To evaluate the effect of *Eladi Churna* in the management of *Amlapitta*.

OBJECTIVE: 1. to study the concept of *Amlapitta* as per as *Ayurvedic* text and their discussion with current medical prospective.

2. To evaluate clinically the effect of *Eladi Churna* in the management of *Amlapitta*.

MATERIALS AND METHODS:

***Aushadhi Yoga* :** *Eladi Churna* (*Bharat Bhashajya Rattanakar Part 1/41*)

TABLE NO-1: Showing the ingredient of *Eladi churna*:

Name	Rasa	Guna	Virya	Vipaka	Doshagh nata	Karmukata
<i>Ela</i> (<i>Elettaria Cardamomum</i>)	<i>Katu, Madhura</i>	<i>Laghu, Ruksha</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Tridosha hara</i>	-
<i>Vamshalochana</i> (<i>Bambusa arundiaceae</i>)	<i>Madhura, Kashaya</i>	<i>Ruksha, Laghu, Tikshana</i>	<i>Sheeta Except Patra & Phala</i>	<i>Madhura</i>	<i>Vata-pitta shamaka</i>	<i>Trishna nigraaha, balya, brimhana</i>
<i>Dalchini</i> (<i>cinnamomum Zeylanicum</i>)	<i>Katu, tikta, madhura.</i>	<i>Ruksha, Laghu, Tikshana</i>	<i>Ushna</i>	<i>Katu</i>	<i>Va-takaphan ashka</i>	-
<i>Haritaki</i> (<i>Terminalia chebula</i>)	<i>Panchrasa except lavana</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Tridosha hara, Ra-sayana</i>	<i>Shothahara, Raktastambaka, Vedanasthapana</i>
<i>Amalaki</i> (<i>Embellica Officinalis</i>)	<i>Panchrasa except Lavana</i>	<i>Guru, Ruksha, Sheeta</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Tridosha hara esp pit-tashamak a</i>	<i>Deepana, Pachana, Dahaprashamana, Anulomana</i>

<i>Pippali (Piper Longum)</i>	<i>Katu</i>	<i>Laghu ,Snigdha,Tikshna</i>	<i>Anushna sheeta</i>	<i>Madhura</i>	<i>Va-takapha-hara</i>	<i>Rasayana,Vrishya, Shoolaprashamana</i>
<i>Chandana (Santalum Alba)</i>	<i>Tikta, Madhura</i>	<i>Laghu, Ruksha</i>	<i>Sheeta</i>	<i>Katu</i>	<i>Pit-tashamaka,, Kaphash amaka</i>	-
<i>Tejpatra (cinnamomum Tamala)</i>	<i>Madhura, katu</i>	<i>Laghu, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>	<i>Kaphagh na</i>	-
<i>Dhaniya (Coriander Sativum)</i>	<i>Ka-saya, Tikta, Katu, Madhura</i>	<i>Laghu ,Snigdha</i>	<i>Ushna</i>	<i>Madhura</i>	<i>Tridosha maka</i>	<i>Agnimandhya ,Ajeerna, Shothahara, Shoolahara ,Deepana, Pachana, Rochana</i>
<i>Mishri (Saccharam Officinarum)</i>	<i>Madhura</i>	<i>Laghu ,Snigdha</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>VataPit-tashamaka</i>	<i>Ruchikara, Dahahara, Shukrala</i> ^{7,8}

Dose : 3 gm ,Twice a day

Ausadhi Sevana kaal :Purvabhakta

Route of Administration :Orally

Anupana : Luke warm water

Duration : 60 Days

Follow Up : After every week

METHOD:

- **Centre of study** :Jammu institute of Ayurveda Rughnalya ,Jammu.
- **Method of Sampling:** Simple Randomised.
- **Study design:** Prospective Open Non comparative.
- **Source of Data:** The study was conducted in single group clinically and pathologically diagnosed selected from the O.P.D and I.P.D of J.I.A.R.

INCLUSION CRITERIA:

- The Patients having classical sign and symptoms of *Amlapitta* as mentioned in *Ayurvedic* texts like:*Hritkantha dahaha,Amlodgar,Trishna.Aruchi ,Klama,and Avipaka.*

- Patients belonging to both sexes.
- The patients of *Amlapitta* irrespective of caste and socio-economic status will be included under the study.

EXCLUSION CRITERIA:

- Patients who have undergone Gastric surgeries.
- Known cases of Gastric and duodenal ulcers.
- Patients with Gastric Malignancies.
- Gastritis with others systemic disorders.

CRITERIA FOR ASSESSMENT

a)SUBJECTIVE PARAMETERS:Patient was diagnosed on the basis of *Amlapitta lakshanas* as described in *Ayurveda* Classics

1. *Tikta Amlodgara*
2. *Aruchi*
3. *Avipaka*
4. *Adhmana*
5. *Utklesha*
6. *Gaurava*
7. *Klama*

b)OBJECTIVE PARAMETERS: Blood - Hb%, T.L.C., D.L.C., E.S.R.

CRITERIA FOR ASSESSMENT OF RESULT:The efficacy of therapy was assessed on the basis of

- Subjective Parameters before and after treatment.
- Objective Parameters before and after treatment.

TABLE NO 2 : Score will be given as follow:

	0	1	2	3	4
1. <i>Tikta Am-lodgara</i>	Absent	Occasional	Once in a week	Once in 2-3 days	Every day
2. <i>Aruchi</i>	Absent	Occasional	Once in a week	Once in 2-3 days	Every day
3. <i>Avipaka</i>	Absent	Occasional	Once in a week	Once in 2-3 days	Every day
4. <i>Adhmana</i>	Absent	Occasional	Once in a week	Once in 2-3 day	Every day
5. <i>Utklesha</i>	Absent	Occasional	Once in a week	Once in 2-3 days	Every day
6. <i>Gaurava</i>	Absent	Occasional	Once in a week	Once in 2-3 days	Every day
7. <i>Klama</i>	Absent	Occasional	Once in a week	Once in 2-3 days	Every day

Grading Of Assessment

Subjective And Objective Parameters Of Baseline Data To Pre And Post Medication Were Compared For The Assessment Of Results. All The Results Were Analysed Statistically By Student Paired -T Test.

Observations And Result: Distribution Of 30 Patients According To Their Sex

Maximum No. Of Patients Were Males I.E.56.66% And 43.33% Of Patients Were Females.

Distribution Of 30 Patients According To Their Addiction

76.66% Patients Were Taking Tea, Maximum Patients I.E. 77% Patients Were Addicted To Tea. 10% Were Addicted To Tobacco While 7% Were Addicted To Alcohol And 3% Had No Addiction At All.

Distribution Of 30 Patients According To Their Time Of Meal

In The Present Clinical Study 53.33% Patients Time Of Meal Was Regular While, 46.66% Patients Were Taking Irregular Diet.

Distribution Of 30 Patients According To Their Agni

Maximum I.E. 73.33% Patients Were Having *Mandagni*, While 26.66% Patients Were Having *Vishamagni*.

Distribution Of 30 Patients According To Their Koshtha

Maximum I.E. 53% Patients Had *Krura Koshtha*, While 37% Patients Had *Madhyama Koshtha* And 10% Patients Had *Mridu Koshtha*.

Distribution Of 30 Patients According To The Chronicity

Out Of 30 Patients 33.33% Were Having The Chronicity Of 0 - 6 Months And 26.66% Patients Had Chronicity Of 6m-Lyr; 16.66% Were Suffering From Lyr - 18 Months, 10% Were Suffering From 18 Months To 2 Year And 6.66% Were Suffering From 2years - 30 Months And 6.66% Patients Were 30m - 3years.

Distribution Of 30 Patients According To Their Vyayama Shakti

Majority Of Patients I.E. 63% Were Bearing *Avara Vyayama Shakti*, While 30% Patients

Were Bearing Madhyama Vyayama Shakti And 7% Were Bearingpravara Vyayama Shakti.

Distribution Of 30 Patients According To Their Jarana Shakti

Majority I.E. 60% Patients Were Having Madhyama Jarana Shakti, While 36.66% Were Having Avara Jarana Shakti And 3.33% Were Pravara Jarana Shakti.

Distribution Of 30 Patients According To Their Abhyavaharana Shakti

83.33% Patients Were Having Madhyama Abhyavarana Shakti And 10% Patients Were Having Avara And 6.66% Pravara Abhyavarana Shakti.

Distribution Of 30 Patients According To Lakshanas

Maximum I.E. 83.33% Patients Had Tikta Amlodgara; 80% Patients Were Suffering From Hrit Kantha Daha And Aruchi; 70% Patients Were Suffering From Gaurava And; 66.66% Patients Had Utklesha; 63.33% Patients Had Avipaka; 60%Patients Had Adhmana; While 33.33% Patients Were Suffering From Klama.

Result:

TABLE NO 3: Effect of therapy on symptoms

Symptoms	Mean BT	Mean AT	Mean Dif-ference	% Re-lief	SD	SE	t- Val-ue	P Value	Significant
<i>Tikta Am-lodgara</i>	3.0	.28	2.78	90.66	0.89	0.18	15.27	<0.001	Highly sig-nificant
<i>Hrit Kantha-daha</i>	2.4	1.1	1.3	54.16	0.75	0.15	8.43	<0.001	Highly sig-nificant
<i>Aruchi</i>	2.86	0.238	2.62	91.67	0.80	0.17	14.914	<0.001	Highly sig-nificant
<i>Avipaka</i>	2.75	0.33	2.42	88	0.93	0.19	12.75	<0.001	Highly sig-nificant
<i>Utklesha</i>	2.53	0.31	2.2	87.74	1.03	0.24	9.34	<0.001	Highly sig-nificant
<i>Klama</i>	2.4	1.4	1.0	41.66	0.47	0.15	6.71	<0.001	Highly sig-nificant
<i>Adhmana</i>	2.95	1.3	1.65	55.93	0.49	0.11	15.08	<0.001	Highly sig-nificant
<i>Gaurava</i>	2.39	0.83	1.55	64.85	0.70	0.17	9.369	<0.001	Highly sig-nificant

TABLE NO 4 : EFFECT OF THERAPY ON OBJECTIVE PARAMETERS

Sr. No	Observations	No of Patients	Mean B.T	Mean A.T	Mean Diff	Relief %	SD	SE	'T' Value	'P' Value	Sig Results
1	Hbgm%	30	12.59	13.05	0.46	-3.65	0.60	0.19	-2.42	<0.02	S
2	ESR	30	25.9	21.4	4.5	17.35	19.19	6.07	0.74	<0.10	N.S
3	TLC	30	69.70	66.00	3.70	5.31	4778.07	1512.04	0.24	<0.10	N.S
4	P	30	65.50	62.60	2.90	4.43	7.6	2.4	1.2	<0.10	N.S

5	L	30	30.10	32.9	-2.8	-9.30	6.30	1.99	1.40	<0.10	N.S
6	F	30	2.10	2.40	-0.30	-4.28	1.56	0.50	-0.6	<0.10	N.S
7	M	30	2.3	2.0	0.3	13.01	3.02	0.96	0.312	<0.10	N.S

TABLE NO 5 : OVERALL EFFECT OF THERAPY ON 30 PATIENTS

RESULT	NO OF PATIENTS	PERCENTAGE
Complete Remission	0	0%
Markedly Improved	17	56.67%
Moderately Improved	09	30%
Mildly Improved	03	10%
Unchanged	01	3.33%

It is evident from the aforesaid data that *Eladi Churna* is Effective.

DISCUSSION

Amlapitta a gastrointestinal disorder caused due to suppression of *Jatharagni* (gastric fire) by increased *drava guna* (liquidity) and *amla guna* (sourness) of *vidagdha pachaka pitta* affects the *Annavaha-Rasavaha-Raktavaha-Purishvaha srotas*, *Samana-Prana Apana Vayu*, mainly *Kledaka* and partially *Bodhaka kapha*. The increasing rate of *Amlapitta* presents a constant challenge to research workers of *Ayurveda*. Several drugs were analysed for its treatment in clinical and experimental study. This includes both single and. Regarding the clinical definition, both the Diseases have similar symptoms like *Tikta -amlo-udgara* i.e. (Eructations with bitter and sour taste), *Hrid-Kantha-daha* can be correlated with (Burning sensation in the chest and throat), *Avipaka* (Indigestion), *Utklesha* (Nausea), *Aruchi* (Loss of appetite), *Klama* (Exhaustion), *gaurava* (feeling of heaviness in the body), *Adhmana* (Fullness in the abdomen). The first line of treatment is the same in Allopathic and *Ayurveda* i.e. Life style modification and avoidance of food stuff which aggravates the condition. In Allopathic system of medicine, Pharmacological treatments are often disappointing. Most experts

advocate a trial of proton pump inhibitor and/or *Helicobacter* if present. The *Ayurvedic* scientists have claimed that natural drug materials or approaches used according to *Ayurvedic* system of medicine are not found to produce any resistance and can be used for longer duration without any side effects . This has encouraged the present scholars to assess the effect of the *Ayurvedic* approaches i.e. both *Shodhana* and *Shamana* treatment in *Amlapitta* The present clinical study was conducted among 30 patients. The patients were assessed on various parameters for obtaining the effect of the therapy. All the clinical signs and symptoms were assessed on the basis of scoring given to them before treatment (B.T.) and after treatment (A.T.). "*Eladi Churna*" was given for duration of 8 weeks. Treatment therapy observed a significant relief in the symptoms of GERD like heartburn, abdominal bloating, abdominal belching, and fullness of stomach after meals, nausea and vomiting after 60 days of treatment with "*Eladi Churna*"^{9,10}.

PROBABLE MODE OF ACTION OF DRUGS

Action of a medicine mainly depends upon its subtle constituents like *Rasa, Guna, Virya, Vipaka, Prabhava*. When the *Rasa* and *Vipaka* are in equal strength then *Vipaka*

dominates over *Rasa* and both *Rasa* and *Vipaka* are superseded by *Veerya* while *Prabhava* overcomes all of them. In "*Eladi Churna*" maximum ingredients have been well indicated in *Pitta* predominant pathologies, Due to this property, it breaks the *Samprapti* of *Amlapitta* and normalizes the state of *Agni*. Doing the function of *Strotovibandhanasana* and action against *Pitta*, it is effective on *Pitta* and *Mandagni*, and provides good results in all signs and symptoms. Thus regulates *Jatharagni*, checks the excessive growth and accumulation of *Pittaagni* and thereby causing results into disease *Pitta*.

Mode of Action according to modern concept

Ela :*Ela* works as Anti - spasmodic and soothes coli. Its volatile oil is laxative and used in wind, dyspepsia and nausea. Its anti - spasmodic activity is through muscarini receptor blockage. Cardamom helps in cleansing of body. It is considered to be a refinement spice against caffeine.

V amshlochana: *Vamshlochana* is having Anti- ulcer activity. It works as cross - linking agent providing strength, flexibility and resilience to collagen and elastic connective tissue.

Twak (Dalchini): *Dalchini* is Anti-oxidant in nature. Its volatile oil i.e.(E) -cinnamyl acetate and (E) -coxyphyllene is also Anti-microbial in nature, against E -coli, salmonella typhi, candida and shigella dysentriae.

Haritaki :*Haritaki* is having Anti-ulcer property. It also works as Anti-secretory agent by lowering activity of H.pylori and decreasing Hcl secretion, hence inc. gastric pH. **Amalaki**: *Amalaki* is having Anti -ulcer, cyto- protective and Anti secretory properties and causes decrease in pyloric -ligation

induced basal gastric secretion. **Pippali** :*Pippali* having an Alkaloid named 'P' penne me. appetite and stimulates enzyme that promotes amino-acid uptake from GIT and inc. heat in GI tract. **Chandana**: *Chandana* works as Anti -ulcer agent especially in stress induced ulcers due to its Anti - histaminic activity. It is also Anti secretory in nature.

Tejpatra :*Tejpatra* lower blood AST and ALT levels and improves liver activity, hence improving digestion. It also inc. activity of Anti - oxidant enzymes in the body.

Dhanyak (Dhaniya): *Dhanyak* mainly protects gastric mucosa from damage, due to free radical screening property of different Anti - oxidant constituents, it also protects gastric mucosa from pylorus ligated accumulation of gastric acid secretion. **Sita**: *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 etc¹¹.

CONCLUSION

On the basis of study Of review of literature, observations noted during study, findings collected after clinical trial and the results obtained after statistical analysis, the following conclusions are drawn.

1. *Amlapitta* (Gastro Esophageal Reflux Disease) is a commonly occurring disease.
2. Clinical manifestations of *Amlapitta* are very close to that of Gastro Esophageal Reflux Disease.
3. *Eladi churna* has shown highly significant results in *Amlapitta* (Gastro Esophageal Reflux Disease)
4. *Eladi Churna* is an effective remedy in uncomplicated and new cases of *Amlapitta*. Therefore it can concluded that

Eladi Churna is very potent drug and can be used effectively in management of *Amlapitta* w.s.r Gastro Esophageal Reflux Disease.

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