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A Comparative clinical study to evaluate the efficacy of *Amalaki churna* over *Yastimadhu churna* with *Sasyaka bhasma* in the management of *Amlapitta* w.s.r to G.E.R.D.

Author name: Dr. Shweta Sindagi

PG Scholar, Department of Kayachikitsa

A.E.A. Ayurvedic Medical College and P.G. Centre, Davangere.

Guide name: Dr. Muktha M.H. M.D.(Ayu)

Professor & H.O.D.

Department of P.G.studies in Kayachikitsa

A.E.A. Ayurvedic Medical College and P.G. Centre, Davangere.

ABSTRACT

In Ayurveda,Agnimandya is the root cause of all the disease.The major reason behind Agnimandya is faulty dietary habits as Adhyasana,Vishamasana,and Vegadharana, leads to vitiation of Doshas either independently or synonymously. In India,prevalence is 7.6 to 30%,being <10% in studies and the dietary factor associates include use of spices and non vegetarian food.

Gastroesophageal reflux is a disease occurring due to improper functioning of esophageal sphincter. It is a very common disease. Patients with gastroesophageal reflux disease (GERD) has the signs and symptoms such as heartburn, chest pain, gastric discomfort, abdominal distension,sour belching, food regurgitation, nausea and reduced appetite.

Amlapitta is one of the most common disorders of the *Annavaha Srotas* described in Ayurveda and is characterized by symptoms such as *Avipaka, Amlodgara, Hrit-Kantha Daha, Utklesha, Gaurava,* and *Aruchi*. In modern medicine, these manifestations closely resemble Gastro esophageal Reflux Disease (G.E.R.D.)**,** which has become increasingly prevalent due to unhealthy dietary habits, stress, and sedentary lifestyle. Although conventional medications provide symptomatic relief, long-term use is associated with recurrence and adverse effects.Hence,there is a need for safe and effective Ayurvedic interventions.

KEY WORDS: *Amlapitta, Agnimandya, GERD, Amalaki Churna*

INTRODUCTION

Amlapitta is one of the most commonly encountered disorders of *Annavaha Srotas* described in Ayurveda. In

the present era of modernization, altered dietary habits, irregular food intake, excessive consumption of spicy, oily and fast foods, stress, sedentary lifestyle and suppression of natural urges have significantly contributed to the increased incidence of gastrointestinal disorders. Among these, Gastroesophageal Reflux Disease (G.E.R.D) has emerged as a major health problem affecting quality of life worldwide. G.E.R.D is characterized by reflux of gastric contents into the esophagus resulting in symptoms such as heartburn, sour regurgitation, chest discomfort, nausea, abdominal distension and indigestion.[1] These manifestations closely resemble the clinical features of *Amlapitta* described in *Ayurvedic* classics.

According to Ayurveda, Agni plays a pivotal role in maintaining health, and impairment of *Jatharagni* is considered the prime cause for the genesis of many diseases. Due to indulgence in *Nidanas* such as *Adhyashana, Vishamashana*, *Ati Amla-Lavana-Katu Ahara Sevana*, stress and improper lifestyle, *Pitta Dosha* undergoes vitiation leading to *Agnimandya*. The improperly digested food undergoes *Vidagdha* and *Shukta Avastha*, ultimately resulting in *Amlapitta*.[2]*Amlapitta* is predominantly a *Pittapradhana Vyadhi* associated with vitiation of *Vata and Kapha Dosha* and manifests with symptoms like *Amlodgara, Hritkantha Daha, Avipaka, Aruchi, Klama, Utklesha* and *Gaurava*.[3] These symptoms show marked resemblance with the clinical presentation of G.E.R.D. The concept of *Amlapitta* has been elaborately discussed in *Ayurvedic* literature. Though *Charaka Samhita* does not describe *Amlapitta* as an independent disease entity, references regarding Amla and *Vidagdha* conditions are available at various places.[4] Sushruta mentioned a condition termed "*Amlika*" produced due to excessive intake of *LavanaRasa*.[5]*Kashyapa Samhita* is considered the first text to describe *Amlapitta* as a separate disease entity with detailed *Nidana*, *Lakshana* and *Chikitsa*.[6]*Madhava Nidana* further explained its etiopathogenesis and classified it into *Urdhwaga* and *Adhoga Amlapitta*.[7]

In contemporary medicine, management of G.E.R.D mainly includes antacids, H2 receptor blockers and proton pump inhibitors. Although these drugs provide symptomatic relief, long-term use is associated with recurrence and adverse effects. Hence, there is a need for safe and effective herbal formulations that can provide sustained relief with minimal side effects. Ayurveda offers numerous formulations possessing *Deepana, Pachana, Pittashamaka and Rasayana* properties beneficial in the management of *Amlapitta*.

AIM & OBJECTIVES

AIM

To evaluate the efficacy of *Amalaki Churna* over *Yastimadhu Churna* along with *Sasyaka Bhasma* in the management of *Amlapitta.*

OBJECTIVES

1.To evaluate the efficacy of *Amalaki Churna* along with *Sasyaka Bhasma* in *Amlapitta.*

2.To validate the efficacy of *Yastimadhu Churna* along with *Sasyaka Bhasma in Amlapitta.*

3.To compare the efficacy of *Amalaki Churna* over *Yastimadhu Churna* Along with *Sasyaka Bhasma* in *Amlapitta.*

MATERIALS AND METHODS

SOURCE OF DATA:

LITERARY SOURCE:

The literary source of the present study was collected from classical, modern literature, websites, magazines, research papers about the disease.

PHARMACEUTICAL SOURCE:

All the medicines needed for the study were procured from GMP certified pharmacy.

Method of Preparation of *Amalaki Churna*

Fresh, fruits of *Amalaki* (*Embilica officinalis* Gaertn./*Phyllanthus embilica* Linn.) were collected and cleaned thoroughly. The fruits were shade dried until complete removal of moisture. After drying, the seeds were removed and the pericarp was powdered using a pulveriser. The powder was then passed through a fine mesh sieve (No. 80)to obtain a uniform particle size. The sieved powder was stored in a clean, dry, airtight container.

Method of Preparation of *Yastimadhu Churna*

The dried roots of *Yastimadhu* (*Glycyrrhiza glabra* Linn.) were procured and cleaned thoroughly. The roots were cut into small pieces and dried further to eliminate residual moisture. They were then powdered in a pulveriser and passed through a fine mesh sieve (No. 80) to obtain a smooth and uniform *Churna*. The prepared powder was preserved in a clean, dry, airtight container.

CLINICAL SOURCE:

40 Patients of *Amlapitta*, were selected randomly from the OPD and IPD of Ashwini Ayurvedic Medical College, Hospital &P G Centre Davangere or its associated hospitals were selected after being screened as *Amlapitta* .

METHODS OF COLLECTION OF DATA:

- 40 patients of either sex, diagnosed as *Amlapitta* were randomly selected for study.
- A case proforma was specially designed with all points of history taking, physical signs, lab investigations as mentioned in classics and allied sciences.
- The parameters of signs and symptoms were scored as mentioned in the proforma.

INCLUSION CRITERIA:

- Patients with Minimum 3 *Pratyatma lakshana* Of *Amlapitta* is included.
- Patients of either sex aged above18 years and below50.
- Patients with diagnosed case of G.E.R.D.

EXCLUSION CRITERIA:

- Patients Aged below 18 and above 50.
- Patients having any systemic disorders such as hypertension, diabetes.
- Patients with Peptic ulcer complications including malignancy

DIAGNOSTIC CRITERIA:

Subjective Criteria

Ref: Arun Mahapatra, Study on clinical efficacy of *Avipattikara Choorna* and *Sutashekara rasa* in the management of *Urdhwaga Amlapitta*. Journal of Pharmaceutical and Scientific innovation April 2015.

Grades Symptoms	0	1	2	3
1.Avipaka	No digestion	Digests normal usual diet in 9 hours	Digests normal usual dietin12 hours	Digests normal usual diet in 24 hours or more
2.Klama	No tiredness	Feel tired after exertion work	Feel tired after normal work	Feel tired even after taking rest
3.Utklesha	No nausea	Feel nausea after eating Some peculiar food	Feel nausea after eating all kinds of food	Full day nausea, not related to eating
4.Tikta amla udgara	No sour&bitter belching	Sour & bitter belching after Taking spicy food	Sour & bitter belching after Taking any type of food	Sour & bitter belching having No relation with food intake
5.Guruta	No feeling of heaviness in the body	Heaviness after taking more quantity of heavy food	Heaviness even after taking light food	Heaviness even on empty stomach
6. Hrit kantha daha	No burning sensation	Burning sensation after intake of spicy food	Feeling of burning sensation even after intake of normal food	Burning sensation even on empty stomach
7.Aruchi	No anorexia	Eat food only two times without any snacks in between	Eat only once	Have no feeling of appetite

WITHDRAWAL CRITERIA:

Increase in symptoms, any allergic reaction or not willing to continue, therefore such Subjects were withdrawn from the study.

STUDY DESIGN:

40 Subjects with *Amlapitta* were taken&randomly divided into 2 groups consisting of 20 subjects in each group.

Group A

- *Amalaki churna* dose-5gms twice daily before food. [Sha.Ma6/2]
- *Sasyaka bhasma* dose-125mgs twice daily before food.[R.T21/130]

- *Anupana: Usnajala*
- Treatment duration:1month
- Follow up: 0, 2nd ,4th week during treatment and5th&6th week after treatment.

Group B

- *Yastimadhu churna* dose-5gmstwicedailybeforefood.[Sha.Ma6/2]
- *Sasyaka bhasma* dose-125mgstwicedailybeforefood.[R.T21/130]
- *Anupana-Usnajala*
- Treatment duration:1month
- Follow up: 0, 2nd ,4th week during treatment and 5th&6th week after treatment.

ASSESSMENT CRITERIA:

The assessment was done on the basis of following Subjective parameters before, during, after the scheduled treatment and after follow up.

- *Avipaka* (indigestion)
- *Klama*(exhaustion)
- *Utklesha*(nausea)
- *Tiktaamlodgara*(erectations with bitter or sour taste)
- *Gaurava*(feeling of heaviness of body)
- *Hritkanthadaha*(burning sensation in chest&throat)
- *Aruchi*(loss of appetite)

STATISTICAL ASSESSMENT:

Student's Paired T test

RESULTS

Table: Relief % after treatment & after follow up of all symptoms

Symptom	Relief % after treatment		Relief % after follow up	
	Group A	**Group A**	**Group B**	**Group B**
Avipaka	**94%**	**89%**	**54%**	**51%**
Klama	**86%**	**72%**	**62%**	**46%**
Utklesha	**85%**	**75%**	**49%**	**40%**
Tiktaamlodgara	**81%**	**74%**	**52%**	**40%**
Gaurava	**90%**	**82%**	**87%**	**57%**
Hritkanthadaha	**65%**	**68%**	**55%**	**58%**
Aruchi	**97%**	**85%**	**68%**	**47%**

Table: Overall effect of the treatment after treatment

Parameters	Criteria	Group A	Group B	Group A %	Group B %
Cured	**100% relief**	**0**	**0**	**0%**	**0%**
Complete remission	**More than 75% relief**	**19**	**14**	**95%**	**70%**
Marked improvement	**51-75% relief**	**1**	**5**	**5%**	**25%**
Moderate improvement	**26-50% relief**	**0**	**1**	**0%**	**5%**
Unchanged	**Below 25% relief**	**0**	**0**	**0%**	**0%**

DISCUSSION

Discussion on Mode of Action of Formulations

1.Mode of Action of *Amalaki Churna* with *Sasyaka Bhasma*

The formulation comprising *Amalaki Churna* and *Sasyaka Bhasma* acts on the fundamental pathology of *Amlapitta*, namely *Agnimandya*, *Ama* formation, and *Pitta Prakopa*. *Amalaki* is described as *Tridoshahara,* with predominant *Pittashamaka* action owing to its *Amla Pradhana Pancharasa* (except *Lavana*), *Sheeta Veerya*, and *Madhura Vipaka*. Although it possesses *Amla Rasa*, its *Madhura Vipaka* and *Sheeta Veerya*

counteract the excessive *Amla* and *Ushna* qualities of aggravated *Pachaka Pitta*, thereby reducing burning sensation, sour belching, and acid reflux.

Amalaki is also a well-known *Rasayana*, which improves the quality of *Rasa Dhatu* and restores the normal functioning of *Jatharagni* without causing *Pitta* aggravation. Its *Laghu* and *Ruksha Guna* facilitate digestion and prevent the accumulation of *Ama*, while its antioxidant and rejuvenating properties promote healing of the gastric and oesophageal mucosa. The *Kashaya* and *Tikta Rasa* further contribute to *Pitta Shamana* and reduce excessive gastric secretions.

Sasyaka Bhasma, possessing *Kashaya-Madhura Rasa*, Laghu *Guna*, *Sheeta Veerya*, and *Madhura Vipaka*, acts primarily as a *Deepana* and *Pachana* drug. It stimulates impaired digestive fire, digests *Ama*, and corrects metabolic dysfunction. Its *Kapha-Pittahara* action helps in reducing excessive *Kleda* and acidic secretions in the stomach.

The combination of *Amalaki Churna* and *Sasyaka Bhasma* thus exerts a synergistic action by correcting *Agnimandya*, pacifying *Pitta Dosha,* eliminating *Ama*, improving digestive and metabolic functions, and promoting healing of the Gastro intestinal mucosa. Consequently, it effectively relieves symptoms such as *Avipaka*, *Tikta-Amlodgara*, *Hrit-Kantha Daha*, Utklesha, *Gaurava*, *Klama*, and *Aruchi*, while also reducing the likelihood of recurrence through its *Rasayana* effect.

2.Mode of Action of *Yastimadhu Churna* with *Sasyaka Bhasma*

The formulation containing *Yastimadhu Churna* and *Sasyaka Bhasma* acts predominantly through *Pitta*shamana, *Vranaropana*, *Shothahara*, and *Brimhana* properties. *Yastimadhu* possesses *Madhura Rasa*, *Guru Guna*, *Sheeta Veerya*, and *Madhura Vipaka*, making it one of the best drugs for alleviating aggravated *Pitta* and *Vata.* Its *Madhura Rasa* and *Sheeta Veerya* provide immediate soothing effects on the inflamed gastric and oesophageal mucosa, thereby reducing burning sensation, irritation, and acid-induced discomfort.

Yastimadhu is well known for its *Vranaropana* properties, which promote regeneration of damaged mucosal tissue and strengthen the protective mucosal barrier. It also possesses *Shothahara* and *Rasayana* actions that reduce inflammation and improve tissue healing. These properties are particularly beneficial in patients with chronic acid reflux and mucosal erosion. Furthermore, its demulcent nature protects the gastric lining from further acid injury and helps alleviate symptoms such as *Hrit-Kantha Daha* and *Tikta-Amlodgara*.
The addition of *Sasyaka Bhasma* complements the action of *Yastimadhu* by providing *Deepana* and *Pachana* effects. It improves digestive fire, digests *Ama*, and reduces *Kapha-Pitta* vitiation, thereby addressing the underlying digestive dysfunction responsible for the disease. Its *Kapha-Pittahara* action also assists in reducing nausea, heaviness, and indigestion.

Discussion on Hypothesis

The present comparative clinical study was undertaken to evaluate and compare the efficacy of *Amalaki Churna* with *Sasyaka Bhasma* and *Yastimadhu Churna* with *Sasyaka Bhasma* in the management of *Amlapitta* with special reference to G.E.R.D.

The comparative analysis showed that 95% of patients in Group-A achieved complete remission compared to 70% in Group-B, and Group-A demonstrated comparatively greater percentage relief in most of the clinical parameters. The second alternative hypothesis (H2)stated that *Amalaki Churna along with Sasyaka Bhasma is more effective than Yastimadhu Churna along with Sasyaka Bhasma in Amlapitta*. The superior efficacy of Group-A may be attributed to the *Rasayana*, *Pittashamaka*, *Agni-Sandhukshana*, and *Ama-Pachana* properties of *Amalaki*, which effectively address the root pathology of *Amlapitta*. Therefore, H2 was accepted.

CONCLUSION

1. *Amlapitta* is primarily a *Pitta Pradhana Tridoshaja Vyadhi* originating from *Agnimandya*, leading to *Ama* formation and vitiation of *Pachaka Pitta*,*Samana Vayu, and Kledaka Kapha*, predominantly affecting the *Annavaha Srotas*.
2. *Nidana Parivarjana*, correction of *Jatharagni*, *Ama Pachana*, and *Pitta Shamana* are the fundamental principles for the successful management of *Amlapitta*. Drugs possessing *Sheeta Veerya*, *Madhura Vipaka*, *Pittashamaka*, and *Rasayana* properties effectively break the *Samprapti* of the disease.
3. Gastro esophageal Reflux Disease (G.E.R.D.) is a chronic acid reflux disorder caused by dysfunction of the lower oesophageal sphincter and impaired gastric physiology. Its clinical manifestations closely resemble *Amlapitta*, supporting the correlation between the two conditions and justifying the Ayurvedic therapeutic approach.
4. The disease was predominantly observed among young and middle-aged adults (21–40 years), with a slightly higher incidence in males, indicating that active working-age individuals are more susceptible due to occupational stress and unhealthy lifestyle practices.
5. The majority of patients had *Vata-Pitta Prakruti*, *Mandagni*, *Madhyama Koshta*, *Madhyama Satva*, and belonged to the middle socioeconomic class, suggesting that constitutional factors along with impaired digestive fire play a major role in the development of *Amlapitta*.
6. Most patients had a history of *Adhyashana*, *Vishamashana*, *Ratrijagarana*, sedentary work, lack of regular exercise, excessive tea/coffee consumption, and psychological stress, emphasizing the importance of dietary and lifestyle factors in the etiopathogenesis of the disease.
7. Both *Amalaki Churna* with *Sasyaka Bhasma* and *Yastimadhu Churna* with *Sasyaka Bhasma* produced highly significant improvement ($p<0.01$) in all the assessed subjective parameters, namely *Avipaka*, *Klama*, *Utklesha*, *Tikta-Amlodgara*, *Gaurava*, *Hrit-Kantha Daha*, and *Aruchi*.
8. The overall therapeutic response showed that 95% of patients in Group-A achieved complete remission, whereas 70% of patients in Group-B achieved complete remission, indicating excellent efficacy of both formulations.
9. Both formulations effectively alleviated the clinical manifestations of *Amlapitta* without producing any adverse effects during the study period.
10. Comparative analysis revealed that *Amalaki Churna* with *Sasyaka Bhasma* was more effective than *Yastimadhu Churna* with *Sasyaka Bhasma*.
11. The trial drugs are safe, easily available, economical,and simple to administer.

Their significant therapeutic efficacy, absence of notable adverse effects, and affordability make them suitable for long-term management of *Amlapitta* w.s.r. to G.E.R.D.

ANNEXURE

Amalaki Churna

YASTIMADHU CHURNA

SASYAKA BHASMA

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