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A Clinical Study to Evaluate the Efficacy of *Phalatrikaadi Kwatha* in the Management of *Amlapitta* w.s.r. to Gastroesophageal Reflux Disease

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ABSTRACT

In today's era Amlapitta is a common disease found mostly in middle aged persons due to faulty dietary habits and changing lifestyle. It hampers the daily routine activities due to its symptoms like heart burn, abdominal pain, loss of appetite, nausea and vomiting. Amlapitta is caused by the increased Drava gunaand Amlaguna of Pachaka Pitta. It affects the Annavaha, Rasavaha, Raktavaha, Purishvahasrotasa. Due to increasing incidence of the disease, scholars of different medical field are working to developvarious means and measures to overcome this burning problem.In allopathic system of medicine Amlapitta cannot be correlated with any specific disease, but its symptoms are found in many disorders such as gastric ulcer, duodenal ulcer, gastroesophageal reflux disease and gastritis commonly named as acid peptic disorder. Acid peptic disorder results from an imbalance between aggressive factors (gastric acid, pepsin) and protective factors (gastric mucus, bicarbonate and prostaglandins). Antacids neutralize acid which is the first line of immunity and thus make the person more prone to various infections. While Ayurvedic approach is Agni vriddhi and Aampachana by various means. So, the present study is aimed at finding effective treatment of Amlapitta (gastroesophageal reflux disease). For the present clinical study 20 patients of Amlapitta were registered from the O.P.D., P.G. Department of Kayachikitsa, Rishikul Campus Haridwar. Phalatrikaadi Kwath was selected for managing the patients of Amlapitta.

KEYWORDS

Amlapitta, Mandagni, Gastroesophageal Reflux disease, Phalatrikaadi Kwatha



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INTRODUCTION

Since long time, infectious (communicable) diseases were the biggest killer diseases globally. But now, the trend is changing towards increased prevalence of chronic diseases with causative factors mostly related to diet and lifestyle. *Ayurveda* is as old as human civilization, it is based on two principles maintaining *healthy state of* the human bodyand curing the disease. Most of the *Vikara* are deeply rooted in faulty habits like improper dietary habits, stress, anger, spicy irritant food, oily foods, etc. and *Amlapitta* is one of them.

Amlapitta is not considered as a separate disease in Bruhatatrai but is mentioned as a symptom in number of diseases by Acharya Charaka. Acharya Kashyapa was the first to give a detailed description of the disease. It is also the first text which has counted the Manasika Bhavas (Psychological factors) as a chief cause of the disease and analyse the basis diseaseon the of Doshika predominance. Kashyapa believed that the disease is caused by vitiation of Tridoshas leading to *Mandagni* and *Amlapitta¹*. He describes it as "Bhishakamohakara" as clinical pictures of many diseases like Parinamshoola. Vidagdhajirna, Annadravashoola, Pittajashoola, Pittaja Grahani are overlapping with Amlapitta so it is very difficult to diagnose it and differentiate it. Whereas *Acharya Madhavakara* has described the disease in detail and classified it on the basis of *Gati i.e.*, *Urdhvaga Amlapitta* and *Adhoga Amlapitta*.

According to Acharya charak Amlapitta develops when Aamvisha, get mixed with *Pitta²*. In Ayurvedic text Mandagni is the main cause of all the Roga including Amlapitta. In allopathic system of medicine Amlapitta cannot be correlated with any specific disease, but its symptoms are found in many disorders such as gastric ulcer, duodenal ulcer, gastroesophageal reflux disease and gastritis commonly named as acid peptic disorder. Acid peptic disorder results from an imbalance between aggressive factors (gastric acid, pepsin) and protective factors (gastric mucus. bicarbonate and prostaglandins). Major causes are H. pylori infection, NSAIDS, psychosocial factors etc. According to NDDIC (National digestive Disease Information clearing house), the prevalence rate of gastritis is 10 million and that of peptic ulcer is 5 million (1987) in India. The frequency of both duodenal and gastric ulcer showed a decline from 1998 to 2008 i.e., from 12% to 2.9% and 4.5 to 2.7%. Antacids are among the one of the most widely used



medicine all over the world. Food and drug Administration (FAD) warned that there is increased risk of fractures with the use of Proton Pump Inhibitor. By taking antacids the person neutralizes acid which is the first line of immunity and becomes more prone to various infections. While in Ayurveda we concentrate more on Agni vraddhi and AamPachan by various means. So there is an open field for Ayurvedic scholars.

The drug selected under the study is *Phalatrikaadi Kwatha* described in *Chakradutta. Phalatrikaadi Kwatha* contains *Triphla, Patol, Kutki* and *Yashti Madhu. Most* of the contents have *Virechan* property. *Yashtimadhu* has *Madhur Rasa, Madur Vipaka* and *SheetaVirya* which act against the excessive *Drava, Tikshna* and *Ushna Guna* of *Pitta.*

AIMS & OBJECTIVES

1) To study the aetiopathogenesis of *Amlapitta*.

2) To evaluate the efficacy of *Phalatrikaadi Kwatha* in the management of *Amlapitta*.3) To study the probable mode of action of

Phalatrikaadi Kwatha in Amlapitta

MATERIALS AND METHODS

The study comprised of 20 patients of *Amlapitta*. The patients were selected from

OPD and IPD of Rishikul campus, Haridwar.

Ethical Committee Approval Number-

UAU/R/C/IEC/2016-17/2

Selection of Sample: -Randomized Sampling

Type of Study: Single Blind

Duration of Study: 45 days

Selection of Drug:

Phalatrikaadi Kwatha

1 Dose: 40 ml

2 Time of administration: two times(during morning and evening)

3 Duration of therapy : 45 days

4 Patients were guided regarding *Pathya/Apathya* regimen.

Assessment & Follow Up

Periodic assessment of the signs and symptoms was done at interval of 15 days for 45 days. A follow-up was done after 15 days to check the recurrence if any, after withdrawing the therapy.

INCLUSION CRITERIA-

1. Classical symptoms of *Amlapitta* as described in *Ayurvedic* texts viz. *Amlodgaar, Tiktodgaar, Kanthadaah, Urahdaah, Aruchi, Utklesha, UdarAadhmaan, Avipaka, Gaurav, Klama, Shiroruk.*

2. Age 20- 60 years.



3. GERD without any metabolic complication.

EXCLUSION CRITERIA-

1. Age group < 20 years and more than 60 years

2. Known case of Gastric and Duodenal ulcer

3. Known case of Gastric carcinoma

4. Chronic gastritis (more than 1 year)

5. Any other chronic illness.

Criteria for Assessment: Subjective parameters were employed for assessment of the impact of the treatment. Following sign and symptoms of *Amlapitta* were looked into for assessment:

- Avipaka
- Klama
- Utklesha
- Tiktaudgara
- Amlaudgara
- Gaurav
- Urahadaha
- Kanthadaha
- Aruchi
- Aadhmaan
- Shiroruka

The above symptoms were graded as below:

None-0Mild-1

Moderate	-	2
Moderate to Severe	-	3
Severe	-	4

INVESTIGATIONS

I. Routine haematological, urine examination carried out to rule out any other pathology.

II. USG (if required).

III. Barium meal test (if needed).

STATISTICAL ANALYSIS

• Wilcoxon Signed Rank Test was applied on the subjective parameters.

• The obtained results were interpreted as:

P> 0.05 Not Significant P< 0.01 &<0.05 significant

P< 0.001 highly significant

RESULTS AND DISCUSSION

Discussion on Disease:

Amlapitta is a disease of Pitta dominancy but in vitiated condition. According to Kashyapa Samhita and other classics this vitiation could happen by four main groups of reasons (Aharaja, Viharaja, Manasika, Agntuka). Subsequently after increase in Drava Guna of Pitta formation of Amla Rasa Pradhana Ama takes place. Two more additional Pitta-vitiating factors i.e. ,Anupa Desha (Ka.Ki. 16/22) and the Varsa Ritu has specifically observed and mentioned by Kahsyapa and Srikanthadatta respectively³. Kashyapa has mentioned such etiological factors of *Amlapitta*, which are *Kapha Prakopa* (*Pitta Prakopa* along with *Kapha*).

Symptom	Median		Wilcoxon	P-Value	% Effect	Result
	BT	AT	Signed Rank W			
AVIPAKA	0	0	-2.428 ^a	< 0.05	52.9	Sig
AMLAUDGARA	0	0	-1.633 ^a	< 0.001	40.0	Highly Sig.
KANTHA DAHA	2	0	-3.066 ^a	< 0.01	68.0	Sig
GAURAV	2	1	-3.002^{a}	< 0.01	51.5	Sig
UTKLESHA	2	0.5	-2.739 ^a	< 0.01	50.0	Sig
KLAMA	3	1	-3.700 ^a	< 0.01	48.8	Sig
ARUCHI	3	1	-3.601 ^a	>0.05	52.1	NS
URAH DAHA	2	1	-3.397 ^a	< 0.001	51.3	Highly Sig.
TIKTAUDGARA	0	0	-1.633 ^a	>0.05	55.6	NS
SHIRO RUKA	2	0.5	-2.877 ^a	< 0.01	56.3	Sig
AADHMAAN	0.5	0	-2.598 ^a	< 0.01	52.4	Sig

Table 1 Efficacy Study of Phalatrikaadi Kwatha

Sharangadhara recognized that in the case of lust (Kama) and anger (Krodha), pulse - a factor, is rapid and in case of somatic anxiety and fear it is weak (Sarangadhara Samhita 1:3:9). This proves the effect of Manasik Bhavas on our body activities. Psychological factors like Kama, Krodha, Shoka etc, leads to Agnidusti. Dusti of Mana or Agni leads to Indigestion ${}^{4}(Su.Su. 46/50)$. In Amlapitta, Agni will be diminished due to the Nidana Sevana. The food which is not properly digested becomes Vidagdha and produces Shuktapaka which is having increased Amla Guna in the stomach. If one has no control on eating due to greed vitiated *Pitta Dosha* finally produces Amlapitta.

DiscussionOnObservations& Results(Table 1):-Statistically highly significant

results were found in 2 symptoms – *Amlaudgara* & *Urahadaha*(p<0.001).

• Statistically significant results were found in 7 symptoms viz. *Avipaka*, *Kanthadaha*, *Gaurav*, *Utklesha*, *Klama*, *Shiroruka and Aadhmaan*.

• Statistically non significant results were found in only 2 symptoms *Aruchi* and *Tiktaudgara*.

Percentage wise maximum effect found KanthaDaha(68%), was on ShiroRuka(56%) and Tiktaudgara (55.6%) followed by Avipaka (52.9%), Adhmana (52.4%)Shiro*ruka* (52.4%).Aruchi (52.1%), Urahadaha (51.3%) Utklesha (50%)**Klama** (48.8 %) and Amlodgara(40%).

Discussion on Probable mode of action of Phalatrikaadi kwatha: Most of the contents of *Phalatrikaadi Kwatha* have *Tikta, Kashaya* and *Madhura Rasa .Madhura, Tikta* and *Kashaya Rasa* are *Pitta Shamaka. Tikta Rasa* and *Kashya Rasa* also pacifies *Kapha Dosha.*

▶ In this drug, 4 ingredients have *Tikta Rasa*. According to *Charaka Samhita*, *Tikta Rasa* is having properties like *Krimighna*, *Dahanashak*, *Agnidipana* and *Pitta Sleshma Upasoshana*⁵.

➤ Yashtimadhu present in it has Madhur Rasa. Madhura Rasa counteract the Tikshna Guna of Vitiated Pitta.It also promotes strength, pacify Pitta and Vata Dosha and useful in Daha. Moreover, Yashtimadhu has Madhur Vipaka, and Sheeta Virya which act against the excessive Drava, Tikshna and Ushna Guna of Pitta.

• Yashtimadhu and Patola relieve the symptoms like Amlodgara, *Tiktodgara*, and *Urahadah*a because of their *Madhura Rasa* and *Tikta Rasa* respectively.

• *Triphala*, because of its mild *Virechaka* property, eliminates the vitiated *Pitta* from the body.

► Vatanulomana property of Haritaki and Amalaki helps in expelling the excessive Vidgdha Pitta from the body.

• Kutaki has Pittarechak property

which also help to eliminate vitiated *Pitta* from body.

▶ In pathogenesis of Amlapitta, Mandagni leads to Ama formation. Haritaki also has Agnideepan property .According to Aacharya Sharangdhara it is the best medicine for Amapachana and alleviates the Srotorodhaby Ushna, Tikshana Guna.

• In Amlapitta natural Rasa of Pitta i.e Katu is. converted into Vidagdha Amla Rasa due to Agnimandhya and by virtue of Dravata increase the Pitta Dosha. Tikta Rasa drugs directly act on the Vidagdha Pitta and convert it into Nirama Pitta. Tikta Rasa decreases the Pitta DravataVriddhi, so it benefits in pacifying symptoms like Utklesha, Amlaudgara and Avipaka.

From the above discussion, we can conclude that *Phalatrikaadi Kwatha* effectively carries out *Samprapati Vighatana* of *Amlapitta*.

CONCLUSION

"Conclusions" drawn from present work are as follows:

• *Amlapitta* is a *Pitta Pradhan Vyadhi* which has clinical features similar to GERD.

• Out of 11 subjective parameters *Phalatrikaadi Kwatha* has shown significant results in 9 parameters.



• As discussed above due to the properties of contents of *Phaltrikadi kwatha* it was found to be effective in controlling symptoms of *Amlapitta*.



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