

CLINICAL STUDY OF SHADDHARAN CHURNA IN AMLAPITTA

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ABSTRACT

Amlapitta is a disease prevalent all over world. The increasing prevalence is constant challenge to medical field. In Ayurveda *Amlapitta* is a very common disease described as a *vidagada pitta*. In *bruhutrayeri* disease is described under *vidgada pitta*. While *laghutrayi* named it as an *Amlapitta* with features like *amloudgara*, *hrudhkanth daha avipak*. This disorder is a big burning issue in today's life because of sedentary lifestyle with food habits like pizza, burger, packed items, stress and chemically affected vegetables, fruits. *Amlapitta* is *annavaha strotas* (GI) disorder resembles with hyperacidity in modern science. In chronic stage it may converts in ulcerative conditions. The aim of present study was to find out efficacy of *shaddharan churna*. A Randomized controlled study of total 60 patients was taken for study which is divided into two groups. After conducting clinical study results and observations were obtained. Statistical analysis shows that trial drug and control drug both were effective to reduce cardinal symptoms. As compared to trial drug control drug is more effective but having more side effects if taken for long periods. So we can say that trial drug is more safe for longer periods with reduce of cardinal symptoms and disease also. Hence taking into consideration of its severity and unique combination named as "*Shadharan Churna*" was taken to prove its efficacy for the satisfactory management of *Amlapitta* in more sophisticated way. It is having *kaphavathara*, *Deepana*, *pachana karma*. As it consists of six drugs and all of them will full fill the criteria to treat the *Amlapitta*, which will give relief to the patient that's why the drug has been selected for this research work.

Keywords: *Amlapitta*, *annavaha strotas*, *shaddharan churna*, pantoprazole, *vidagada pitta*, *bruhatrayeri*, *laghutrayi*

INTRODUCTION

Ayurveda, the most ancient science of the world, considered as *Upaveda* (subsidiary) of *Atharva Veda*, has taken rapid stride over the last few decades in realizing people probe into basics of physical and psychological health related problems of fast changing

life styles. Change in function of *Agni* leads to various diseases as per Ayurvedic texts. It is common for many of us to face a burning sensation in stomach and chest at times. This is in most cases due to excessive secretion of acid in the stomach. In *Ayurvedic*

terminology, this is referred as *Amlapitta*, where vitiation of *Pitta Dosha* occurs along with *Kapha Dosha*. This disease was not described in any text of the *Brihatrayi* but a condition named as “*Vidagdha Jirna*” can be compared with *Amlapitta*. The *Amlapitta* is an established entity from the time of Madhav the famous writer of the book “*Madhav Nidan*” (*Rogavinischaya*). Among the three *Doshas*, *Pitta* plays a key role for the genesis of *Amlapitta*. Improper digestion of *Amla rasa* gives rise to *Amlapitta*. This is a *mohakari* (confusing) disease, which gives up different sign and symptoms in various persons. If we can treat *Agni* we can do a great favor to society. In a demographic survey, its prevalence range observed is about 11% to 38.8% of world population. Malaysia, Mexico, Spain and Yemen reported figures on the top quartile of prevalence, whereas the Asian countries reported prevalence rates in the lowest quartile. It is reported that 7.6% of Indian subjects have significant GERD

symptoms. Rapid socioeconomic development and the westernization of Asian lifestyles, including changes in diet and an increase in average *Amlapitta* and its Management.

Aim and Objectives

1. To compare the efficacy of the trial drug with control drug.
2. To compare the trend of recovery of both the groups.

Drug Review: Criteria for selection of “*Shadharan Churna*” as the trial drug

- A) The drug is purely herbal.
- B) All the ingredients are easily available and cheap.
- C) It is suitable for oral administration.
- D) All the drugs are *Agnivardhak* and *pachak* and *vata pitta shamak* in nature

Physical Analysis of trial drug

Colour – Black **Odor** – Aromatic **Taste** – Astringent, Sweet, Sour, Salty and Bitter

Table 1: Drugs information

Sr. No	Drug	Botanical name	Part used	Quantity
1	<i>Chitrak</i>	<i>Plumbago zeylanica</i>	Root/Root bark	1 part
2	<i>Indrayav</i>	<i>Holarhena antidysenterica</i>	Seeds	1 part
3	<i>Patha</i>	<i>Cyclea paltata</i>	Root	1 part
4	<i>Katuka</i>	<i>Picorhizakurroa</i>	Rhizome	1 part
5	<i>Ativisha</i>	<i>Aconitum heterophyllum</i>	Tubrous root	1 part
6	<i>Abhaya</i>	<i>Terminalia chebula</i>	Fruit pulp	1 part

Composition of Shad-Dharana Churna^{15,16}:

As the name of the compound indicates – *Shad-Dharana Yoga* or *Churna* consists of 6 drugs.

Chitrak – *Plumbago zeylanica*

Indrayav – *Holarrhena antidysenterica* seeds

Patha – *Cissampelos pariera*

Katuki – *Picorrhiza kurroa*

Ativisha – *Aconitum heterophyllum*

Abhya – *Terminalia chebula*

How is it prepared?

The powder of each of the above said 6 drugs is taken in a quantity of 24 *ratti* or 1 *dharana* (roughly 240 mg / between 2.5 to 3 grams). They are mixed together into a homogenous mixture.

Dose:

This churna is taken in a dose of 1 *dharana* per day for 15 days continuously.

How to take?

It should be taken mixed in warm water (or any other vehicle advised by doctor) or as advised by the Ayurvedic doctor

Benefits: *Shad-Dharana churna* is used for effective cure of the below said complaints / diseases:

- *Amashayagata Vata* due to *Amlapitta*
- *Mahavyadhi (Yogaratanakara)* – cures many dreadful diseases
- Rheumatoid Arthritis
- Diabetes
- Skin diseases

- Piles (Haemorrhoids)
- Ascitis
- Flatulence
- Constipation

Source of Data:

- Patients of *Amlapitta* were selected from Hospital as per inclusion and exclusion criteria. Literature review was obtained from Ayurvedic magazines, Journals, Conferences, digital library and website. The raw drug collected from the market under the supervision of *Dravyaguna, Ras-shastra Specialist*.
- **Study Design and Sample Size Calculation**
- It was randomized controlled clinical study which carried out in 60 patients of *Amlpitta*. Patients were divided randomly in two equal groups named Group A (Control Group) and Group B (Study Group). Total duration of study was 15 days.

CLINICAL STUDY:

Annexure-I

Inclusion criteria

1. Classical sign and symptoms of *Amlapitta*.
2. Aged between 20 to 60 Yrs. of either sex.

Exclusion Criteria:

1. Below 20 yrs. and above 60 Yrs. of age.
2. Chronic APD, GERD, Gastric Ulcer and other systemic disorder like Malignancies or Hepatic, Renal problem.
3. The patients having known cases of peptic ulcer Diabetes mellitus, Cardiovascular diseases, Ca-Esophagus, Alcoholic patients, Duodenal ulcer, Tuberculosis, Chronic Smoker, Pregnant Woman and lactating mothers.
4. Patients having poorly Controlled blood pressure >160/100 mm Hg
5. Patients having *Annadrava* or *Parinaam Shula*.
6. Patients are on prolonged medication like cortico steroids are rejected.

Grouping and Randomization of Patients

60 patients were selected by simple randomized sampling method; these 60 patients were randomly divided into two equal groups i.e. 30 each.

Investigation:

1. Routine blood investigation –CBC.
2. Gastric Analysis, endoscopy if necessary.
3. Urine routine and microscopic analysis.

Drug Administration Details: Patients of Group A were administered pantoprazole 40 mg orally while patients of Group B were administered *shadharna Churna* along with *koshna Jal* for 15 days.

CRITERIA OF ASSESSMENT: A proforma was prepared with all the points of history taking and examination based on criteria mentioned Ayurvedic classics. Assessment of the effect of treatment was done on the basis of relief in the clinical Symptoms of the disease. Scoring pattern was adapted to assess the relief in the Symptoms.

Subjective parameters:

1. *Avipak* (Indigestion), 2. *Utklesha*, 3. *Klama*, 4. *Gourava*, 5. *Hrut-Kantadaha*, 6. *Tikta Amlodara*, 7. *Aruchi*,
8. *Shiroshula*,

Annexure-II

Objective criteria:

1. *Utklesha* (Nausea)
2. *Klama* (Fatigue)
3. *Gourava* (Feeling of heaviness)

Jeerna Ahara lakshana:-

Utsaha, laghuta, Udgara Shuddhi, trishan pravritti, and yathochit malotsaraga.

1 Avipak (Indigestion) – G0 - natural appetite for food after 5- 6 hrs of ingestion of mixed Indian food
G1 -appetite for food after 7- 8 hrs of taking food
G2 - appetite for food after 9 – 10 hrs of taking food
G3 - appetite for food after 10 – 12 hrs of taking food

2 Utklesa (nausea)

1. Normal: Absent
2. Mild: In relation with Specific food
3. Moderate: In relation with normal food
4. Severe: Associated with chardi (vomiting)

3 Klama: (exhaustion without any exertion)

1. Normal: Absent
2. Mild: Fatigue due to exertion and relived by rest
3. Moderate: Fatigue without exertion more in the morning
4. Severe: Fatigue associated with heaviness

4 Gourava (Feeling of heaviness)

1. Normal: Absent
2. Mild: Feeling heaviness in early morning
3. Moderate: feeling heaviness associated with avipaka
4. Severe: Feeling heaviness associated klama

5 Hritkantadaha (Burning Sensation in chest and throat)

1. Normal: Absent
2. Mild: degree of daha (burning Sensation) in hrudaya and kanatha Pradesh
3. Moderate: degree of daha that subsides after taking sweet/milk/antacids
4. Severe: degree of daha which may relived after vomiting

6 Tikta amlodgara (eructation with bitter and sour taste)

1. Normal: Absent
2. Mild: Tikta amlodagara which subside in an hour
3. Moderate: Tikta amlodgara associated with hrillsaa (nausea)
4. Severe: Tikta amlodgara associated with Kanthdaha

7 Aruchi :- loss of appetite

1. Normal: Absent
2. Mild: Loss of interest in taking food
3. Moderate: Aversion towards food
4. Severe: Nausea after intake of food

8 Shirosula:- Headache

1. Normal: Absent
2. Mild degree of shirosula
3. Moderate degree of shirosula
4. Severe degree of shirosula

Assessment of total effect of therapy:

- A. Unchanged = 25% relief in Symptoms of (Below) Amlapitta.
- B. Encouraging response = 25 to 50% relief of in Symptoms of Amlapitta.
- C. Markedly improved / encouraging response:-More than 50 to 80% reliefs.
- D. Cure/ Excellent response: - 100% relief.

Statistical Analysis:

Collected data properly classified in the form of graph, tables and charts were represented basic

demography was presented in percentage. Further statistical analyses were achieved for subjective criteria with the help of Wilcoxon signed Rank test within the group for results obtained before and after treatment. Mann Whitney 'U' test were applied to compare the results between two groups.

Result:-

The effect of therapy was analyzed statistically and furnished in the dissertation.

Withdrawal Criteria

- a. Patients who discontinued the treatment.
- b. Patients who were unwilling to take the treatment during the study.
- c. Patients show any types of adverse effects.
- d. If any complications occurs

5. OBSERVATION & RESULTS:

In this study 60 patients of 'Amlapitta' were studied. All these patients were diagnosed with the help of criteria of diagnosis. Specially designed Case Report Form (CRF) was used to fill the all information of subjects. Patients attending Kayachikitsa O.P.D of the hospital were examined prior to the start of treatment with respect to the Performa. All these values were termed as before treatment values. (B.T)

After complete examination treatment was started while patients were assigned randomly in two groups. Viz Trial Group which was treated with shadharana Churna along with koshna jala & it is considered as Experimental group (Group-A). While in another group Tab pantoprazole allocated and considered as Control Group B). After completion of therapy all values of these investigations and examinations were recorded, it was termed as after treatment (AT). All these observations were statistically analyzed and results obtained are presented as follows.

- 1) Total number of patients recruited in the study - 60
- 2) Number of patients who completed study - 60
- 3) Number of patients in Exp. Group - 30
- 4) Number of patients in Control group - 30

Number of patients enrolled in the study in the beginning and number of patients dropped out are tabulated accordingly

Table 2: Showing demographic observation

Geographic observation	Predominance	Percentage	No. of patients
<i>Vaya</i>	30-50 yrs	21.5%	13
<i>Linga</i>	Females	38.33%	23
Socio-economic status	Middle class	56.66%	34
Onset of disease	Gradual	43.33%	26
Incidence of aggravation factors	Hunger/spicy food	41.66%	25
Incidence of relieving factors	Medicines	33.33%	20
Addiction	Tea	36.66%	22
<i>Agni</i> (Digestion capacity)	<i>Mandagni</i> (less)	35%	21
Mental status	Stressed	25%	15
<i>Prakruti</i> (nature of patient)	<i>Pitta Kaphaja</i>	25%	15
Site of <i>Udarshoola</i>	Epigastrium	35%	21
Chronicity	<2 year	40%	24
Nature of <i>Udarshoola</i>	Recurrently burning	23.33%	14
Family history	Present	51.66%	31
Habitat	<i>Anupa</i>	51.66%	31
Nature of work	Private job	25%	15

Table 3: Showing before and after percentage in both groups

sr. No.	Symptoms	Experimental Group				Control Group			
		BT	AT	Diff	%of relief	BT	AT	Diff	% of relief
1	<i>Avipaka</i>	73	33	40	54.79	67	39	28	41.79
2	<i>Utklesha</i>	82	35	47	57.31	79	39	40	50.63
3	<i>Klam</i>	82	33	49	59.75	79	38	41	51.89
4	<i>Gaurav</i>	82	34	48	58.53	66	39	27	40.90
5	<i>Hridhkantha daha</i>	56	33	23	41.07	61	30	31	50.81
6	<i>Tiktoamloudgara</i>	60	29	31	51.66	58	34	24	41.37
7	<i>Aruchi</i>	54	32	22	40.74	74	35	39	52.70
8	<i>Shirsoola</i>	61	30	31	50.81	70	39	31	44.28

Figure 1: showing percentage of results

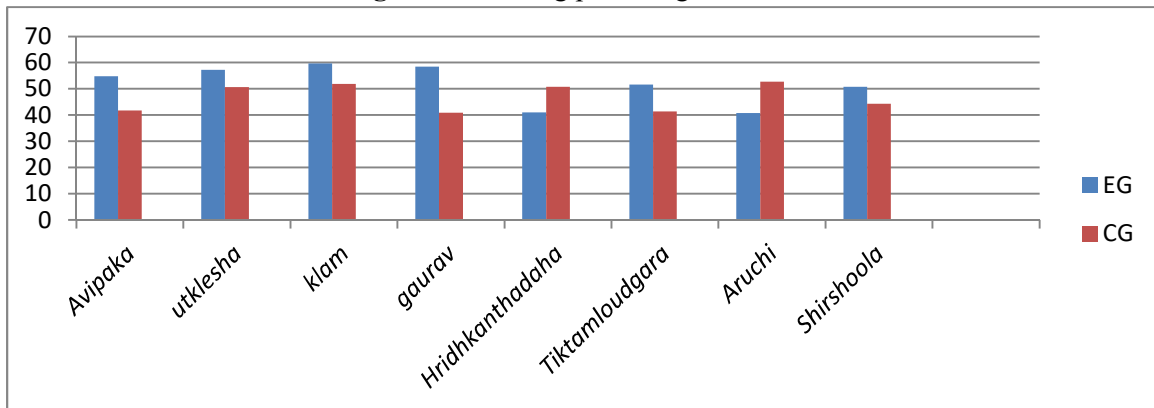


Table 4: Effect of therapy

Sr.no.	Effect Of Therapy	No. Of Patients			Percentage %		
		EG	CG	total	EG	CG	total
1	Cure/ Excellent response(80-100%relief)	00	00	00	00	000	00
2	Markedly Improved 51-80%	09	08	17	30	26.66	28.28
3	Encouraging response 25-50 %	17	14	31	56.66	46.66	51.66
4	Unchanged <25%	05	07	12	16.66	23.33	19.99

In Experimental Group, 09 [30%] patients were markedly improved, 17 [56.66] were having Encouraging response, 05 [16.66%] patients were having no improvement in study.

In Control Group, 08 [26.66%] patients were markedly improved, 14 [46.66%] were having Encouraging response, 07 [23.33 %] patients were having no improvement in the study.

Totally, 17 [28.28%] patients were markedly improved, 31 [51.66%] were having Encouraging response, 12 [23.33%] patients were having no improvement in the study.

DISCUSSION

There are various medicaments are available to treat this disease but result is unsatisfactory on long term use, due to their adverse effect. Review of research work shows that no such clinical research had been carried on this typical disease with respect to the present trial drug that is “*Shaddharan churna*”. All the six drugs are *deepan*, *pachan tridosahar*, and *rasyana* and mostly we can use this combination in *vataanubandhi Amlapitta*. This formulation acts very good results with its *guna*.

Many a times the simple *Agnimandya* leads to *Vidagdhajirna* in the initial stages and if it is neglected, leads to *Amlapitta*. *Amlapitta* is a disease caused due to vitiation of certain attributes of *Pitta* like the *Drava guna* (fluidity) and *Amla guna* (sourness) causing *Vidagdhajirna* at the initial stages and later causes inflammation and corrosion of the *Sleshmadhara kala* of the *Amashaya*, i.e. mucous membrane of the stomach and duodenum.[4] In modern science it can be correlated that *Vidagdhajirna*, a type of simple dyspepsia and *Amlapitta* as gastritis.

Acharya Madhav described this disease as a separate chapter and *Acharya* Kashyap described it with its management. *Amlapitta* is a *Pitta* predominant disease. The cardinal features of *Amlapitta* are *Avipaka*, *Klama*, *Utklesha*, *Tiktoamlodgara*, *Gaurava*, *Aruchi*, *Hritkanthadaha*. With the trial drug, there was a symptomatic relief in the patients i.e. improvement in *Avipaka*, *Tikta Amla Udgara*, *Hridakanthadaha*, *Utklesha*, *Aruchi*, *Vamana* and *Udarashoola*.

Out of 60 patients of *Amlapitta* In Experimental Group, 09 [30%] patients were markedly improved, 17 [56.66] were having Encouraging response, 05 [16.66%] patients were having no improvement in study.

In Control Group, 08 [26.66%] patients were markedly improved, 14 [46.66%] were having Encouraging response, 07 [23.33 %] patients were having no improvement in the study.

Patients treated with trial group shows 28% patients had shown maximum improvement and 51% patients were moderately improved. This implies that *shaddharan churna* may be considered as an effective drug for *Amlapitta*. As *Amlapitta* is a chronic condition it needs a long period study. Statistically it has been observed that the trial drug is significantly effective to reduce all the sign and symptoms of *Amlapitta*.

CONCLUSION

Ayurveda is gaining more popularity among common man all over the world. People are demanding drugs with lesser side effects. Modern drugs are creating more complications rather than their effects. So, need of hour is to find alternate drug from *ayurveda* in acid peptic diseases. *Shaddharan Churna* is giving promising result in *Amlapitta*, so could replace the modern drug like pantoprazole. Study on larger pool

of patients give way to use of this drug by *Ayurvedic* fraternity at larger scale. Research is needed for various drug dosage forms of *Shaddharan Churna*.

Scope of further study

- This trial was a time bound limited study of 15 days so an extended long term trial is required comparing both the drugs for better comparison.
- The cost of trial drug can brought down by massive production.
- Since the recurrence rate of GERD after PPI treatment is significant so an extension of trial to include the recurrence rate may show better efficacy of trial drug.
- The mode of action of the drug is not clear as such. It needs a further study.

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