



A PLACEBO CONTROLLED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF *JEERAKADHYA GHRITA PRAYOGA* IN *AMLAPITTA* WITH SPECIAL REFERENCE TO *URDHVAGA AMLAPITTA*

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ABSTRACT

Amlapitta is a disease of *Annavaha srotas* which is characterized by the symptoms like *Avipaka*, *Klama*, *Utklesha*, *Tikta Amlodghara*, etc. explained by *Acharyas*. It is the most disturbing and irritable condition. As the *Nidana* leading to impairment of *Pachakagni* causes many diseases like *Ajeerna*, *Aruchi*, *Agnimandya*, *Amlapitta* etc. *Agni* is responsible for digestion of food. *Amlapitta* is *Pittapradhana Tridoshaja Vyadhi*. Because of the vitiation of *Pitta* there is *Mandagni*. *Ghrita* which is claimed to be *Pittashamaka*, *Dahashamaka* and *Agnideepaka*. So, in the present study the *Jeerakadhya Ghrita* was taken to treat the *Mandagni* and vitiated *Pittadosha*. *Jeerakadhya Ghrita*, mentioned in *Bhaishjya Ratnavali* and *Chakradatta* by the virtue of its *Rasa*, *Guna*, *Veerya*, *Vipaka* and *Samyoga* helps in *Pitta Shamana*, *Daha Shamana*, *Agni Deepana*, and *Ama Pachana*. In the present study, 30 patients diagnosed with *Urdhvagha Amlapitta* were selected randomly and allocated to Group A and Group B. Group A received Placebo capsule and Group B *Jeerakadhya Ghrita*. Group A with placebo was studied to compare the efficacy of *Jeerakadhya Ghrita* was done. Results were analyzed statistically. The study proves that

Jeerakadhya Ghrita has a significant effect in Urdhvagha Amlapitta and Non-Digestible Cellulose used as a placebo has no significant effect in Urdhvagha Amlapitta.

Keywords: Amlapitta, Jeerakadya Ghrita, Placebo, Non-Digestible Cellulose capsule.

INTRODUCTION

The word *Amlapitta* comprises of two words i.e. “Amla” and “Pitta”. *Chakrapani* defines *Amlapitta* as, “*Amlapittam Cheti Amla Gunodriktam Pittam*” i.e., *Amlaguna Udrikta Pitta* is called as *Amlapitta*.¹ *Acharya Madhavakara* explained the *Nidana* and *Samprapti* of the disease in detail as, *Pitta* gets aggravation because of its own aggravating factors and *Nidanas* like *Viruddha*, *Dusta*, *Vidahi*, *Pitta Prakopaka Pana* and *Anna* and produces the disease *Amlapitta*, which is characterized by the symptoms like *Avipaka*, *Klama*, *Utklesha*, *Tikta Amlodghara*,² etc. In modern medicine *Amlapitta* can be compared with many of the GIT disorders including from Dyspepsia to GERD. The symptoms like heartburn, nausea, vomiting, abdominal distention etc. symptoms found in the many of the GIT disorders. Heartburn is commonly complained by up to 45% of the population and the incidence of dyspepsia is nearly 25% of the population and is also associated with abdominal discomfort at least 6 times daily, but only 10-20% out of them consults a physician. Functional dyspepsia accounts for 60% of cases of dyspepsia. Indigestion is very common that 80% of the population will have had indigestion at some time³. The treatment modalities explained by *Acharyas* in *Amlapitta* are *Nidan Parivarjana*, *Shodhana*, *Shamana*, *Langhana* and *Pachana*. Based on the chronicity and the *Dosha* involvement *Chikitsa* can be carried out. In the present study, *Jeerakadhya Ghrita* mentioned in *Bhaishjya Ratnavali*⁴ and *Chakradatta*⁵, was studied to know the efficacy of the *Jeerakadhya Ghrita* with Placebo for the comparison.

Materials and Methods

Source of Data:

- Literary materials were collected from the available *Ayurvedic* and Modern Medical texts, Medical Journals and from electronic media.

- A good quality of *Jeeraka*, *Dhanyaka*, *Go Ghrita*, *Musta*, *Haritaki*, *Vibhitaki*, *Amalaki*, and *Haridra* were purchased from the market.
- Cellulose filled capsules were prepared in the college pharmacy.
- Diagnosed cases of *Amlapitta* from the OPD and IPD of R.P.K. *Ayurvedic Hospital Ilkal*, were selected for the trial, based on inclusion criteria.

Research Design: A placebo controlled comparative clinical study between two groups with 15 patients in each group.

Sample Size: 30 patients were selected for the clinical trial and 15 patients were allocated randomly to Group A and Group B respectively.

Grouping: Group A – Placebo controlled (Capsules filled with Cellulose), Group B – *Jeerakadya Ghrita*.

Diagnostic Criteria: Based on the clinical features explained in classical texts of *Ayurveda* such as,

Major Symptoms

1. *Avipaka*;
2. *Tikta/ Amla Udgara*;
3. *Hrit/ Kantha Daha*;
4. *Utklesha*;
5. *Chardi*

Minor Symptoms

1. *Klama*;
2. *Gourava*;
3. *Aruchi*;
4. *Shirashula*

The patients were diagnosed as suffering from *Urdhvaga Amlapitta*, those presenting with at least 3 of the major and 2 of the minor complaints.

Inclusion Criteria:

- Patients diagnosed as *Urdhvaga Amlapitta*, as per diagnostic criteria.
- Patients of age between 16-60 years.
- Patients were included in the trial with their written consent.

Exclusion Criteria:

- Patients presenting with *Bahudosha Avastha* that required *Shodhana Chikitsa*.
- Pregnant and puerperal women.
- Patients suffering with the CA stomach, gastric/duodenal ulcers.

- Chronicity for more than one year.
- Patients with a history of hematemesis, melena and other systemic disorders that may interfere with the clinical trial.
- Patients receiving medicines for other conditions that interfere with the clinical trial.

Intervention:

Group A:

● Placebo	:	Non-Digestible Cellulose filled capsules (500 mg each)
● Anupana	:	Sukhoshna jala.
● Time	:	Twice daily, (Pragbhakta) 15-30 minutes before meals.
● Diet	:	As per classical recommendation.

Group B:

- Jeerakadya Ghrita : 10 gms.
- Kalpa : Ghrita (Sneha kalpana).
- Anupana : Sukhoshna jala.
- Time : Twice daily, (Pragbhakta) 15-30 minutes before meals.
- Diet: As per classical recommendation.

Study duration:

- Treatment/Trial: 30 days. (for both groups)
- Follow up period: 30 days (two follow-ups at 15th

and 30th day after the completion of the trial), (for both groups, with placebo administration). The Non-Digestible Cellulose filled capsules were used as Placebo, one capsule twice daily 15-30 minutes before meals will be administered.

- Total duration of study: 60 days.

Assessment Criteria: 4-point scale was used for grading the severity of the individual parameters and overall severity of the condition.

Table 1: Assessment Criteria.

Grade	Severity
0	Absent / Normal
1	Mild
2	Moderate
3	Severe

Subjective Parameters: Assessment of the following parameters before treatment, after treatment and at the end of the follow up.

1. Avipaka.

- Normal, takes normal time to digest food - Grade 0
- Takes 4-6 hour for digestion of food - Grade 1
- Takes 6-9 hour for digestion of food - Grade 2
- Takes more than 9 hours for digestion of food- Grade 3

2. Klama

- Absent - Grade 0
- For 1-2 hours, immediate after meal - Grade 1
- Till complete digestion of the food - Grade 2
- Continuous irrespective of digestion - Grade 3

3. Utklesha

- Absent - Grade 0
- Present after heavy meals, but subsides by own

- Grade 1
- Present with normal food with sour/ bitter belching - Grade 2
- Present even on empty stomach and feels relieved by vomiting (induced) - Grade 3

4. Hrut/Kanta Daha

- Absent- Grade 0
- Present only after consumption of Ushna, Teekshna, and Amla Padartha - Grade 1
- Present even with intake of routine meals and relieved only after digestion of food - Grade 2
- Present even with intake of routine meals and relieved only by vomiting or antacids - Grade 3

5. Tikta/Amla Udghara

- Absent - Grade 0
- Amla/ Tikta Udghara only on consumption of Amla, Katu, Vidahi Padartha- Grade 1

c. *Amla/ Tikta Udghara* with normal food, associated with *Hrut/Kanta Daha*– Grade 2.

d. *Amla/ Tikta Udghara* even on empty stomach, associated with *Utklesha* – Grade 3.

6. *Gourava*

a. Absent – Grade 0

b. Present after heavy meals, confined to abdomen region for a short period– Grade 1

c. Present after normal meals, abdomen heaviness lasts for more than 2 hours – Grade 2

d. Present even with small quantity of food, generalized feeling of heaviness – Grade 3

7. *Aruchi*

a. Absent – Grade 1

b. *Aruchi* towards food, but can eat– Grade 1

c. *Aruchi* towards food, but can eat very little forcibly – Grade 2

d. *Aruchi* towards food, forcible consumption leads to nausea, and vomiting on occasions– Grade 3

8. *Chardi*

a. Absent – Grade 0

b. Patient vomits only bilious contents– Grade 1

c. Patient vomits partially digested food particles without any odour– Grade 2

d. Patient vomits non-digested food particles with foul smell – Grade 3

9. *Shirashula*.

a. Absent – Grade 0

b. Occasional, not interfering the daily activities– Grade 1

c. Occasional, leads to disturbance for daily activity and subsides only after rest – Grade 2

d. Continuous, not relieved by rest and requires active medication for the pain relief – Grade 3

As no objective parameters are available in classical text, assessment was done by only subjective parameters.

Statistical Analysis

- Results were analyzed statistically by using Wilcoxon signed rank test. The data was collected in the form of Mean, SD, SE, ‘P’ value and ‘z’ value. The values were compared Before Treatment/After Treatment, Before Treatment / Follow Up, After Treatment / Follow Up, within groups.

- And the significance with each parameter were compared with each group After Treatment and Follow Up.

Observations and Results: Observations for the present study were done in two stages. Generalized observations for overall patients. Result related observation for individual groups was done before treatment, after treatment and at the end of the follow up.

Table 2: Showing data related to statistical analysis of GROUP A

Variable	Grading on	Mean	SD	SE	Variable	Grading on	Z value	p value	Sign
<i>Avipaka</i>	BT	1	0.92	0.24	<i>Avipaka</i>	BT/AT	-1.890	0.059	NS
	AT	0.66	0.72	0.18		BT/ FU	-1.633	0.102	NS
	FU	0.73	0.79	0.2		AT/ FU	-1.000	0.317	NS
<i>Klama</i>	BT	1.26	0.79	0.2	<i>Klama</i>	BT/AT	-2.236	0.025	S
	AT	0.93	0.79	0.2		BT/ FU	-2.000	0.046	S
	FU	1	0.84	0.22		AT/ FU	-1.000	0.317	NS
<i>Utklesha</i>	BT	1.06	0.70	0.18	<i>Utklesha</i>	BT/AT	-1.890	0.059	NS
	AT	0.73	0.59	0.15		BT/ FU	-1.000	0.317	NS
	FU	0.93	0.79	0.2		AT/ FU	-1.342	0.18	NS
<i>Hrit/Kantha Daha</i>	BT	1.8	0.67	0.17	<i>Hrit/Kantha Daha</i>	BT/AT	-1.890	0.059	NS
	AT	1.6	0.73	0.19		BT/ FU	-1.342	0.18	NS
	FU	1.6	0.73	0.18		AT/ FU	-1.414	0.157	NS
<i>Tikta/Amla Udghara</i>	BT	1.26	0.88	0.23	<i>Tikta/Amla Udghara</i>	BT/AT	-1.732	0.083	NS
	AT	1.06	0.79	0.21		BT/ FU	-.577	0.564	NS
	FU	1.2	0.77	0.2		AT/ FU	-1.000	0.317	NS
<i>Gourava</i>	BT	1.33	0.64	0.16	<i>Gourava</i>	BT/AT	-2.000	0.046	S
	AT	0.87	0.74	0.19		BT/ FU	-1.890	0.059	NS

Aruchi	FU	0.8	0.77	0.2	Aruchi	AT/ FU	-.447	0.655	NS
	BT	1.13	0.99	0.25		BT/AT	-2.714	0.007	HS
	AT	1.13	0.35	0.09		BT/ FU	-2.588	0.01	S
Chardi	FU	0.33	0.48	0.13	Chardi	AT/ FU	-1.732	0.083	NS
	BT	0.06	0.25	0.07		BT/AT	-1.000	0.317	NS
	AT	0	0	0		BT/ FU	-1.000	0.317	NS
Shirashula	FU	0	0	0	Shirashula	AT/ FU	.000	1.00	NS
	BT	1.53	0.74	0.19		BT/AT	-2.333	0.020	S
	AT	1.06	0.88	0.23		BT/ FU	-2.000	0.046	S
	FU	1.26	0.96	0.24		AT/ FU	-1.134	0.159	NS

Table 3: Showing data related to statistical analysis of Group B

Variable	Grading on	Mean	SD	SE	Variable	Grading on	Z value	p value	Sign
Avipaka	BT	0.86	0.83	0.21	Avipaka	BT/AT	-2.762	0.006	S
	AT	0.066	0.25	0.06		BT/ FU	-2.714	0.007	S
	FU	0.266	0.45	0.12		AT/ FU	-1.732	0.083	NS
Klama	BT	1.46	0.74	0.2	Klama	BT/AT	-3.213	0.001	HS
	AT	0.4	0.50	0.13		BT/ FU	-3.213	0.001	HS
	FU	0.4	0.50	0.13		AT/ FU	.000	1.00	NS
Utklesha	BT	1.26	0.79	0.20	Utklesha	BT/AT	-3.153	0.002	HS
	AT	0.13	0.35	0.09		BT/ FU	-3.357	0.001	HS
	FU	0.4	0.63	0.16		AT/ FU	-2.000	0.046	S
Hrit/Kantha Daha	BT	2.2	0.56	0.14	Hrit/Kantha Daha	BT/AT	-3.573	0.000	HS
	AT	0.06	0.25	0.06		BT/ FU	-3.442	0.001	HS
	FU	0.93	0.45	0.12		AT/ FU	-3.606	0.000	HS
Tikta/Amla Udghara	BT	1.6	0.63	0.16	Tikta/Amla Udghara	BT/AT	-3.419	0.001	HS
	AT	0.6	0.50	0.13		BT/ FU	-2.640	0.008	S
	FU	0.93	0.25	0.06		AT/ FU	-2.236	0.025	S
Gourava	BT	1.33	0.72	0.19	Gourava	BT/AT	-3.276	0.001	HS
	AT	0.4	0.50	0.13		BT/ FU	-3.217	0.001	HS
	FU	0.33	0.48	0.12		AT/ FU	-.577	0.564	NS
Aruchi	BT	0.86	0.83	0.21	Aruchi	BT/AT	-2.739	0.006	S
	AT	0	0	0		BT/ FU	-2.598	0.009	S
	FU	0.13	0.35	0.09		AT/ FU	-1.414	0.157	NS
Chardi	BT	0.4	0.63	0.16	Chardi	BT/AT	-2.121	0.034	S
	AT	0	0	0		BT/ FU	-2.236	0.025	S
	FU	0.06	0.25	0.06		AT/ FU	-1.000	0.317	NS
Shirashula	BT	1.8	0.94	0.24	Shirashula	BT/AT	-3.025	0.002	HS
	AT	0.73	0.45	0.11		BT/ FU	-3.051	0.002	HS
	FU	1.06	0.59	0.15		AT/ FU	-1.890	0.059	NS

BT-Before Treatment, AT-After Treatment, FU-Follow UP, NS-Nonsignificant, S-Significant, HS-Highly significant

Table 4: Comparative efficacy of Group A and Group B, Before and After treatment.

Result	Symptoms (Group A)	Symptoms (Group B)
NS (non-significant)	It showed non-significant effect on the symptoms- <i>Avipaka, Utklesha, Hrit/Kantha Daha, Tikta/Amla Udghara, and Klama.</i>	None of the symptoms were observed in non-significant effect.
S (significant)	It showed significant effect on the symptoms- <i>Klama, Gourava and Shirashula.</i>	It showed significant effect on the symptoms- <i>Avipaka, Aruchi and Chardi.</i>
HS (highly significant)	It showed highly significant effect on the symptom <i>Aruchi.</i>	It showed highly significant effect on the symptoms- <i>Klama, Utklesha, Hrit/Kantha Daha, Tikta/Amla Udghara, Gourava, and Shirashula.</i>

Highly significant effects in six parameters with *Jeerakadhya Ghrita* against only 1 parameter with Placebo indicates positive pharmacological efficacy of

Jeerakahya Ghrita against the psychological advantage of the placebo control group in the trial period.

Table 5: Comparative efficacy of Group A and Group B, After treatment and Follow up

Result	Symptoms (Group A)	Symptoms (Group B)
NS (non-significant)	It showed non-significant effect on all the parameters.	It showed non-significant effect on the symptoms- <i>Avipaka, Klama, Gourava, Aruchi, Chardi and Shirashula</i> .
S (significant)	None.	It showed significant effect on the symptoms- <i>Utklesha and Tikta /Amla Udghara</i> .
HS (highly significant)	None.	It showed highly significant effect on the symptom- <i>Hrit/Kantha Daha</i> ,

The non-significant effect in 6 parameters in the period of follow up, where in the patients of both groups were administered with NDC capsules again

proves that the *Jeerakadhya Ghrita* showed positive response in the trial period and the same effect was sustained in the follow up period.

Table 6: Comparative effect on Group A and Group B, Before treatment and Follow up

Result	Symptoms (Group A)	Symptoms (Group B)
NS (non-significant)	It showed non-significant effect on the symptoms- <i>Avipaka, Utklesha, Hrit/Kantha Daha, Tikta/Amla Udghara, Gourava and Chardi</i> .	None of the symptoms were observed in non-significant effect.
S (significant)	It showed significant effect on the symptoms- <i>Klama, Aruchi and Shirashula</i> .	It showed significant effect on the symptoms- <i>Avipaka, Tikta/Amla Udghara, Aruchi and Chardi</i> .
HS (highly significant)	None of the symptoms were observed in highly significant effect.	It showed highly significant effect on the symptoms- <i>Klama, Utklesha, Hrit/Kantha Daha, Gourava, and Shirashula</i> .

Highly significant effect in 5 parameters with *Jeerakadhya Ghrita* in the total 60 days duration of the study proves confirmative evidence regarding the therapeutic values of *Jeerakadhya Ghrita* in *Urdhvagha Amlapitta*. The study proves with the hypothesis that *Jeerakadhya Ghrita* has a significant effect in *Urdhvagha Amlapitta* and Non-Digestible Cellulose capsule used as a placebo has no significant effect on *Urdhvagha Amlapitta*.

DISCUSSION

The disease *Amlapitta* is not found to be explained as a separate disease in *Bhruhatryi*. The detailed description regarding the disease is available in *Laghutrayi*. Few scattered references of the term *Amlapitta* can be seen in *Brihatrayi*. In the period of *Bhruhatryi* it may not be much of a disturbing disease, as there was advancement and changes in lifestyle, *Amlapitta* might have developed as a disease in the period of *Laghutrayi*. *Amlapitta* is a *Pittapradhana*

Tridoshaja Vikara, here mainly aggravation of *Pitta* along with *Kapha* and *Vata*. The *Nidan*s like *Viruddahara, Adhyashana, Ajeerna, Vegavarodha, Bhukte Bhukte Snana, Avagahana, Diwaswapna* and *Antarodaka Pana*⁶, etc. leads to formation of *Ama* and in turn causes impairment in *Annavaha Srotas* and ultimately produces the disease *Amlapitta*. The disease can be treated by the drugs which are having the properties i.e. *Tikta* and *Kashya Rasa, Madhura Vipaka, Laghu* and *Ruksha Guna, Pitta* and *Kapha Shamaka Dravyas*. In the present study, *Jeerakadhya Ghrita* was used as a trial drug to evaluate its efficacy in *Amlapitta*. The ingredients are *Jeeraka, Dhanyaka* and *Murchita Go Ghrita* which are having the properties like *Katu, Tikta, Kashaya* and *Madhura Rasa*, helps to pacify *Pitta* and *Kapha Dosha*. The *Gun*s like *Laghu* and *Ruksha* pacifies *Kapha Dosha*; *Snigdha Guna* helps in digestion by doing *Agnideepana (Kledana)*. *Katu Vipaka* pacifies *Kapha Dosha* and brings back the normal *Rasa* of *Pitta*.

Sheeta Virya pacifies *Pittadosha* and *Ushnavirya* acts as *Agnideepaka* by increasing its *Teekshna Guna* and also does *Kapha Shamana*. Both the drugs *Jeeraka* and *Dhanyaka* are having *Deepana* and *Pachana Karma*. The *Ghrita* is *Sheeta Virya* and *Madhura Vipaka* acts as *Pitta* and *Daha Shamaka*. This *Ghrita* when processed with *Deepana* and *Pachana Dravyas* acquires the *Deepaka*, *Pachaka* and *Pittashamaka* attributes due to its *Sanskarasyanuvartana* property. So, the *Jeerakadya Ghrita*, with the synergetic action of all its ingredients, reduced the symptoms of *Urdhwaga Amlapitta*.

CONCLUSION

Amlapitta is a psychosomatic disorder either it may be because of *Aharaja*, *Viharaja* or *Manasika Nidana*. So, in the present study *Jeerakadhya Ghrita* and Non-Digestible Cellulose capsules to see the effect of both drugs in the patients. It was found that those who were suffering with psychological stress and strain showed significant effect with Non-Digestible Cellulose capsules. It was observed that in 1 month of the treatment period, patients showed excellent response with the *Jeerakadhya Ghrita*, but in the follow up period when we put patients on Non-Digestible Cellulose capsules for next 1 month, there was aggravation of symptoms. By this we can say that it is *Yapyavyadhi* which can be treated with *Pathyapathya* and *Shamanoushadis*. In severe conditions it is essential to expel the *Doshas* through *Shodhana chikitsa*.

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