

Fundamental and Clinical Study to Evaluate Efficacy of Drakshadya Ghrita on Amlapitta

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ABSTRACT

Introduction: Ayurveda's fundamental concepts are based on the Sankhya philosophy of universe creation, according to which man is a Microcosm of a Universe within himself. The introduction of external factors into the human body's internal environment happened by *AGNI* (Digestive element). All diseases are caused by to defacement of *Agni*. (1) Also *Amlapitta* is a disease caused by a disruption in the *Agni* level. The classical literature on *Amlapitta* explains that *Amlapitta* is such a condition in which *Drava guna* and *Amlaguna* (sourness) of *Pachak Pitta* (Gastric juice) increase which is normal for *Katu rasa* (bitter taste). (2) Acharya Vagbhat in *Ashtang Hriday Samhita* has explained basic fundamentals for *Vataj*, *Pittaj*, and *Shleshmajvyadhichikitsa*. *Ghrita* is par excellent (*parma-aushadha*) *Shamana Dravya* for *pitta Dosha*. (3) *Drakshadya Ghrita* is the most effective formulation of *Ghrit Kalpana* mentioned for *Amlapitta* in *Yogratnakar Samhita*. (4)

Material and Method: *Drakshadya Ghrita* was prepared by *Yogratnakar Formulation*. Open Clinical trial of *Drakshadya Ghrita* was conducted on 45 patients of given inclusion criteria for 10 days with these Assistent criteria - *Hrutkanthdaha*, *Avipaka*, *Utklesh*, *Amlodgar*, *Gaurava*, *Agnimandya*.

Observation and Result: Effect on *Agnimandyasymptoms*, Mean 1.06 before treatment which is reduced to 0.11, SD score was 0.96 before treatment which is reduced to 0.31 and Median score was 1 reduced to 0 after treatment after follow-up up with 89.62 % improvement, and there is a statistically significant change ($p < 0.0001$ HS).

Discussion: Patients had shown improvement in all the criteria of assessment of *Amlapitta*. No adverse effect was observed. Thus *Drakshadya Ghrita* can be recommended for the management of *Amlapitta*.

Keywords: *Drakshadya Ghrita*, *Agni*, *Amlapitta*, *Shodhan*, *Shaman*

Introduction: Ayurveda's fundamental concepts are based on Balanced *Agni* is the key to living a long, healthy and fulfilling life whereas impaired *Agni* is a surefire way to court imbalance, disease and discontent. *Amlapitta* is a disease of *Annavaastrotas*(5) (Digestive System) occurs by the vitiation of *Athat* can be found in any corner of the world. People now a days practise incorrect nutrition and lifestyle due to a lack of understanding of *AshtauAahar Vidhi Vishesha Ayatan* (Concept of Dietics)(6), *Aaharvidhi Vidhan* (Concepts of food intake) (7), *Viruddhahara* (incompatible food)(8) and *Asatmya Ahara*, Improper following of *Dincharya* and *Rutucharya*. However, in this fast-food era, people are willing to overlook everything in order to attain their goal. No gain without pain, So Hurry, worry, stress, strain, and anxiety are all on the table. All of them accelerate the vitiation of dosha by disturbing action of *Agni* leads resulting in *Hrutkanthdaha*, *Amlodgaar*, *Avipaka* like symptoms.(9) This is in most

cases due to excessive secretion of acidic material in the stomach. In Ayurvedic terminology, this is referred to as *Amlapitta*, where vitiation of *Pitta Dosha* occurs along with *kapha Dosha* (10). According to Modern therapy it is better to consider *Amlapitta* as a syndrome (acid reflux syndrome) (11) rather than a particular gastrointestinal disease. Sign and Symptoms of *Amlapitta* closely resembles with gastritis, (12) non-ulcer dyspepsia, (13) hyperchlorhydria, (14) as well as hypochlorhydria (15) and in chronic stage, it may lead to gastric ulcer. Modern medicine uses H₂ blockers and proton pump inhibitors for symptoms of this disease, which shows remarkable relief in symptoms, but long-term use of H₂ blockers and proton pump inhibitors causes side effects like dizziness, headache, gynaecomastia, loss of libido, temporary oligospermia, atrophic gastritis etc. (16)

The disease's peculiarities include its high prevalence, wide range of symptom manifestations, and the need for long-term dietary control. If not treated in a timely manner, it can lead to serious complications, and relapses are common. In a demographic survey, its prevalence range observed is about 11% to 38.8% of world population. (17) Rapid socioeconomic development and the westernization of Asian lifestyles, including changes in diet and an increase in average body mass index, are likely to be the key factors in change in epidemiology.

Even though *Amlapitta* is not a dreadful disease but it hampers day-to-day activity of the patient. This work was aimed to see the efficacy of *Drakshadya Ghrita* in *Amlapitta* as *Shamakyoga*. Contents of this Yoga are easily available, cost-effective and easy for preparation because of all these reasons this formulation was selected.

Aim: To evaluate the fundamental and clinical efficacy of *Drakshadya Ghrita* in *Amlapitta*.

Objectives:

1. To study the fundamentals about the efficacy of *Drakshadya Ghrita* in *Amlapitta*.
2. Evaluate the efficacy of *Drakshadya Ghrita* on *Hrud-daha*, *Avipaka*, *Gourava*, *Utklesh*, *Amlodgara* and *Agnimandya*.

METHODOLOGY

1. Material:

This clinical study is registered in the Clinical Trial Registry of India, ICMR, New Delhi (CTRI; www.ctri.nic.in). Trial Acknowledgement Number is REF/2021/06/044226 and explained as per the consolidated standards of reporting trials statement 2021.

- **Literature Study material**

Literary aspects of the study will be collected from Ayurvedic books with recent medical journals and internet. All the fundamentals related to vitiated Pitta and Ghrita.

- **Clinical Study Material:**

Drakshadya Ghrita which is described under *Amla Pitta Chikitsa Rogadhikar* of *Yogratnakar* was taken as trial drug in the present study.

2. Collection of Raw Drug :

Raw drugs were collected from the Manas Ayurved, Ghatate Layout, Civil lines, Nagpur.

3. Identification and Authentication :

Raw drugs of Drakshadya Ghrita were identified and authenticated by Department of Dravya Guna .

4. Drakshadya Ghrita Preparation

Drakshadya Ghrita preparation in 3 steps

- 1) Ghrita Murchana :
- 2) Ghrita Paka with medicine
- 3) Ghrita Pariksha

Table Showing Ingredients and their weights used for GhritaMurchana

Sr. no	Ingredients	Measurements
1	Amalaki	285.71 gm
2	Haridra	285.71 gm
3	Mustaka	285.71 gm
4	Haritaki	285.71 gm
5	Bibhitaki	285.71 gm
6	Manjishtha	285.71 gm
7	Matulungswarasa	285.71 gm
8	Goghrita	5 kg
9	Jala	20 liters

Procedure of making GhritaMurchana :

Kalkawas prepared from all the drugs coarse powder by adding Matulungaswarasa . In a large iron vessel with wide mouth Goghrita was taken and heated over Madhyamagnitill complete evaporation of moisture content become possible at the temperature around 140oC. The Kalka was added to the Ghrita after slight cooling, at temperature around 85oC. When Kalka becomes light brown in color, water was added in proportion to 4 times of Sneha. After addition of water, it was heated on Mandagni with intermediate stirring. Heating duration was adjusted so as to complete the Snehapaka till Sneha Siddhi Lakshana appeared and then SnehaPaka is complete. Then vessel was taken out from the fire and Ghritawas filtered through clean cloth in its mild hot stage. Murchita Sneha was stored in a glass jar container after cooling .’

Total loss of Go-ghrita on Murchana :

Initial Amount of Goghrita – 5 Kg
 Obtained MurchitaGoghrita – 4.6 Kg
 Loss – 400gm

2. Ghrita Paka with Medicine :

Table showing Ingredient of DrakshadyaGhrita and its quantity

	Drugs	Latin Name	Family	Part used	Quantity
1	Draksha	Vitis vinifera	Vitaceae	Fruit	95.83 gm
2	Abhaya	Terminalia Chebula	Combrataceae	Fruit	95.83 gm

3	Kutaj	Holerrhenaantidysentrica	Apocynaceae	Bark	95.83 gm
4	Patol	Trichosanthes dioica	Cucurbitaceae	Panchang	95.83 gm
5	Ushir	Vetiveriazizanoides	Graminae	Root	95.83 gm
6	Dhatri	Emblica officinalis	Euphorbiaceae	Fruit	95.83 gm
7	Yava	Hordeum vulgare	Graminae	Seeds	95.83 gm
8	Chandan	Santalum album	Santalaceae	Heartwood	95.83 gm
9	Traymana	Gentiana Kurroa	Gentianaceae	Root	95.83 gm
10	Padmak	Prunus cirasoidus	Rosaceae	Stem bark	95.83 gm
11	Chirayta	Swertia chirata	Gentianaceae	Panchang	95.83 gm
12	Dhanyak	Coriandrum Sativum	Umbelliferae	Seeds	95.83 gm
13	Ghrita				4.6 kg
14	Jala				18.4 liter

Showing Sneha Siddhi Lakshana during DrakshadyaGhrita Preparation

Sr.No	Sneha Siddhi Lakshana	Kalka	Ghrita
1	Sonya eve niryase	+	-
2	Darvi Vimunchati	+	-
3	Shabda hino Agni Nikshipt	-	+
4	Phenashanti	-	+
5	Gandh Varna Rasotpatti	-	+

Finished Product Laboratory Analysis :

Test	Result
Description	Greenish brown coloured Greasy ghrita with fragrant smell and sweet – bitter taste
L. O. D. AT 110 d.c.	0.78 %
REFRACTIVE INDEX AT 40 D.C.	1.344
SPECIFIC GRAVITY	0.942
ACID VALUE	1.750
SAPONIFICATION VALUE	225.880
IODINE VALUE	32

Sample size calculation:

$$\text{Formula: } \frac{z_2 \cdot 1-\alpha/2 \cdot P(1-P)}{d_2}$$

where,

P = Expected proportion

d = absolute precision

1- $\alpha/2$: Desired confidence level

Considering effect of DrakshadyaGhrita on symptoms of Daha reported in previous chart with following assumption :

1)Anticipated effects of DrakshadyaGhrita = 50%

2)Absolute precision (%) = 15%

3)Desired confidence level (1- α) % = 95

4)Required sample size for a study is 45

Statistical Tests:

1. Paired t – test for objective Parameters.
2. Wilcoxon signed Rank test for subjective parameters.

Diagnostic Criteria:

Amlapitta affected patients will screen via pre-assessment criteria base on general sign and symptoms of *Amlapitta*.

Inclusion Criteria:

- Patients age between 18 and 60 years.
- Patients having signs and symptoms of *Amlapittasuch as Daha ,Avipak , Utklesh , Amlodgara , Gaurava , Agnimandya* will selected.
- Patients who gives written consent.

Exclusion Criteria:

- Patients of age <18 years and >60 years.
- Patients already diagnosed with or having any history of other systemic diseases such as cardiovascular ,nephropathic , neuropathic , Diabetes Mellitus and any type of malignant disorders will excluded.

Statistical Analysis:

Subject parameters will be express in frequency and percentage subjective parameters will be compared before and after treatment by performing wilcoxon sign rank test. P< 0.0.5 will be considering as statistical significance statistical software STATA vention 14.0 will be used for data analysis.

Gradings of Assessment ::

<i>Pramukh Vedana</i>	Gradation	Mark
<i>Hrutkanth daha</i>	<ul style="list-style-type: none"> • No burning sensation • Sensation of warmth on throat occasionally • Burning sensation on throat and chest 	<p>0</p> <p>1</p>

	<ul style="list-style-type: none"> after spicy food Feeling of burning sensation always. 	2 3
<i>Avipaka</i>	<ul style="list-style-type: none"> No indigestion Unable to digest mild fatty food Unable to digest 3-course meal (breakfast, lunch and dinner) Unable to digest any kind of food 	0 1 2 3
<i>Utklesh</i>	<ul style="list-style-type: none"> No nausea Mild nausea Severe nausea Severe nausea with Vomiting 	0 1 2 3
<i>Amlodgar</i>	<ul style="list-style-type: none"> Feeling No belching Feeling of belching with no sound Feeling of belching with mild sound Feeling of belching with severe sound. 	0 1 2 3
<i>Gaurav</i>	<ul style="list-style-type: none"> Normal Feeling of heaviness in morning Feeling of heaviness in morning and evening after food Feeling of heaviness Always 	0 1 2 3
<i>Agnimandya</i>	<ul style="list-style-type: none"> Normal Only takes lunch and dinner Loss of interest in lunch or dinner No desire to take food 	0 1 2 3

Observation and Results:

- Fundamental Study Observation :**

<i>Pitta Guna</i>	<i>Ghrita Guna</i>
<i>Teekshna</i>	<i>Mridu</i>

<i>Ushna</i>	<i>Sheeta</i>
<i>Ssneha</i>	<i>Snigdha</i>
<i>Katu,Amla</i>	<i>Madhur</i>
<i>Drava</i>	<i>Snigdha</i>
<i>Laghu</i>	<i>Guru</i>
<i>Vistram</i>	<i>Special Fragrance</i>
<i>Vidahi</i>	<i>Avidahi</i>
<i>Karma – Pachan</i>	<i>Karma – Deepan</i>
<i>When get vitiated cause Agnimandya</i>	<i>Agnivardhak</i>

Ghritha have Pittashamakproperties , properties that are opposite to *Pitta guna* and *Karma* . *Pitta* have mildsneha and dravain nature while *Ghrita* called *Mahasneha* (Best in *Sneha Dravyas*).The outcomes were measured before and after the completion of the treatment by assessment criteria. Data analysis consisted of two parts,

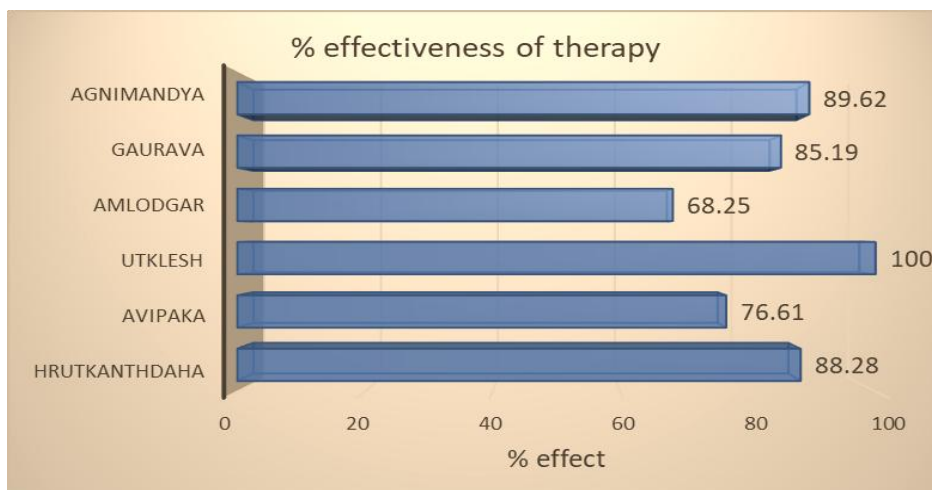
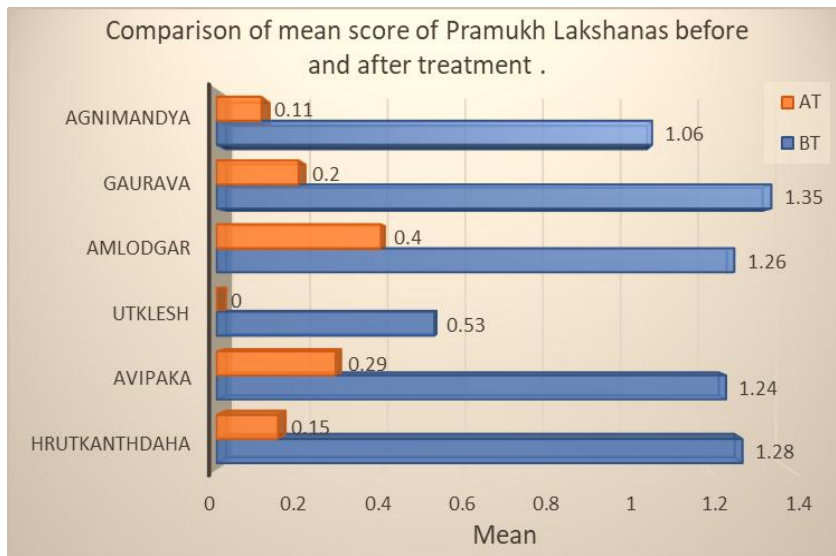
- To describe the characteristics of the subjects by using descriptive methods with help of general points like age, sex, diet, *Prakruti*, *Vyasan*, etc
- Comparison of before-treatment measurements of the outcomes with that of after- treatment.

Showing Stastical presentation of Comparison of mean ,SD , Median score , % Effectiveness of Therapy of *Pramukh Lakshanas* before and after treatment .

Symptom	BT			AT			% effect	Z-value	p-value
	Mean	SD	Median	Mean	SD	Median			
<i>Hrutkanthdaha</i>	1.28	0.84	1	0.15	0.42	0	88.28%	5.836	<0.000 1 HS
<i>Avipaka</i>	1.24	1.02	1	0.29	0.45	0	76.61%	5.484	<0.000 1 HS
<i>Utklesh</i>	0.53	0.52	0	0	0	0	100%	4.558	<0.000 1 HS
<i>Amlodgar</i>	1.26	1.00	2	0.40	0.58	0	68.25%	5.343	<0.000 1 HS
<i>Gaurava</i>	1.35	1.04	1	0.20	0.40	0	85.19%	5.458	<0.000 1 HS
<i>Agnimandya</i>	1.06	0.96	1	0.11	0.31	0	89.62%	5.321	<0.000 1 HS

	BT	AT
<i>Hrutkanthdaha</i>	1.28	0.15
<i>Avipaka</i>	1.24	0.29
<i>Utklesh</i>	0.53	0
<i>Amlodgar</i>	1.26	0.4
<i>Gaurava</i>	1.35	0.2
<i>Agnimandya</i>	1.06	0.11

% Effectiveness of Therapy	
Hrutkanthdaha	88.28
Avipaka	76.61
Utklesh	100
Amlodgar	68.25
Gaurava	85.19
Agnimandya	89.62



DISCUSSION:In this discussion part, the observations of the study was analyzed as follows.

1) Effect on Amlodgara :

This *Lakshana* is mainly due to *Vata Pitta Dosha*. When there is *Vidagdata* and *Shuktatha* of *Aahara* then there is *Amla Udgara*. Statistical analysis showed that the mean score which was 1.26 in

before treatment, was reduced to 0.40 in after treatment, and there is a statistically significant change. (P<0.001)

2) Effect on *Hrutkanthdaha*:

This *Lakshana* is mainly due to *Pitta Dosha*. When there is *Vidagdata* and *Shuktatha* of *Aahara* then there is *Hrutkanthdaha*. Statistical analysis showed that the mean score which was 1.28 in before treatment, was reduced to 0.84 in after treatment, and there is a statistically significant change. (P<0.001)

3) Effect of *Avipakaain Amlapitta*

Avipaka is developed mainly because *Kapha Dosha*. Statistical analysis showed that the mean score which was 1.24 in before treatment, was reduced to 0.29 the after treatment and there is a statistically significant change. (P<0.001)

4) Effect of *Gaurav in Amlapitta*

Gaurav is developed mainly because *Kapha Dosha*. Statistical analysis showed that the mean score which was 1.35 in before treatment, was reduced to 0.20 the after treatment and there is a statistically significant change. (P<0.001)

The treatment was given for 10 days with *DrakshadyaGhrita* as *shaman* which was highly significant. The treatment modalities are safe and are of therapeutic value. The above said observations indicate that patients have shown improvement in all the criteria of assessment of *Amlapitta*. The therapeutic effects like normalcy of *Agni*, Gain of strength are due to decrease of the *Amlapitta* symptoms. The ultimate effect will be curing the *Agnimandya* and correction of *Agni*.

CONCLUSION: The following conclusions are drawn from the clinical study undertaken with *Shamana* in *Amlapitta* through *DrakshadyaGhrita*.

1. Faulty dietary habits and sedentary lifestyle are main contributing factor in the establishment of disease. Excess intake of *Amla*, *Katu Rasa Dravyas* and food articles like *Dadhi*, *Masha*, *Drava Aahara* were the commonest aetiological factors found in this study.
2. The present study was carried for a limited time and it showed encouraging result. No adverse effects were reported by any of the patients.
3. *DrakshadyaGhrita* gives remarkable improvements in *Hrutkanthdaha* (88.28%), *Avipaka* (76.61%), *Amlodgar* (68.25%), *Utklesh* (100%), *Gaurav* (85.19%), *Agnimandya* (89.62%) and overall effect of treatment 84.65%. It is statistically significant.
4. The present study has shown significant results in all types of *Amlapitta* and highly effective in *Amlapitta*.
5. It was found to be effective in *Amlapitta* of mild and moderate severity.

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