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To evaluate the clinical efficacy of *Drakshadi Gutika* in the management of *Urdhwaga Amlapitta* (Non Ulcer Dyspepsia)

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ABSTRACT

Amlapitta is a condition where *Amla Guna* of *Pachaka Pitta* increases due to *Samata* causing *Vidahi* condition. Gastritis and non-ulcer dyspepsia have been correlated with *Amlapitta* by several M.D. and Ph.D. Scholars of Ayurveda. In recent years there has been an unprecedented increase of incidences related to gastro intestinal system due to changing life style like diet pattern, behavioural pattern and mental stress and strain. The prevalence rate of gastritis in India is around 10 million. *Ayurveda* is having good answer to *Amlapitta*. Ayurvedic physicians are providing cure for the patients of these chronic dyspeptic disorders. *Yogartnakar* has said that *Drakshadi Gutika* cures severe *Amlapitta*. *Drakshadi Gutika*, containing *Draksha*, *Haritaki*, *Sita* are having *Madhura*, *Kashaya*, *Tikta Rasa* and *Pitta Shamaka*, *Pitta Rechana Gunas*. These drugs are cost effective, easily available and have a good palatability. So, the present study has been planned to evaluate the clinical efficacy of *Drakshadi Gutika* in the management of *Urdhwaga Amlapitta* (Non Ulcer Dyspepsia).

Key words: *Urdhwaga Amlapitta*, *Non Ulcer Dyspepsia*, *Gastritis*, *Drakshadi Gutika*

INTRODUCTION

Today's life style is completely changed by all the means our diet pattern, life styles, mental stress, strain and behavioural pattern is changed and it is not suitable for our normal physiology of digestion of body. 25 - 30% peoples are suffering from dyspepsia.

These diseases are chronic in nature and affecting to adults mostly. Patients of gastritis often results into

peptic ulcer. Charaka has explained the sequential progression of diseases of G.I.T. to which *Sangraha Granthakara* has given a separate disease status.^[1]

In *Samhita*, *Amlapitta* is not mentioned as a separate disease entity but there are several references in Charaka, Shushruta and Vagabhata *Samhita* regarding *Amlapitta*. *Laghutrayi* have described this disease as a separate entity with detailed description. Later workers followed the same. *Kashyapa*^[2] has accepted the involvement of three *Doshas* in *Amlapitta* while *Madhavakara* has accepted the dominance of *Pitta* in this disease.^[3] This disorder is the result of *Grahani Dosh*. Gastritis and non-ulcer dyspepsia have been correlated with *Amlapitta* by several M.D. and Ph.D. scholars of Ayurveda.^{[4][5]}

Ayurveda has a lot to offer in this regard. Ayurvedic physicians are providing cure for the patients of these chronic dyspeptic disorders. Several single and compound drugs has been tried in this disease. *Shodhana* procedure has not given a due importance in

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this disease by *Sangraha Granthakara* as *Shodhan* is the only procedure in *Bahudoshaavastha*.

As *Shodhan* removes the vitiated *Doshas* from the body from the roots but in *Amlapitta* a small amount of *Hetusevan* can relapse of the same *Lakshanas* seen in *Amlapitta*, hence the study was concentrated on *Shaman Chikista* in *Amlapitta* by using *Drakshadi Gutika* from *Yogratnakar*^[6] to check the efficacy of *Drakshadi Gutika* in *Urdhwaga Amlapitta* and to assess any other associated benefits as well as side effects. A good number of research works have been carried out on *Amlapitta* at various institutes of Ayurveda and many of the clinical trials have proved effective to some extent but failed to provide satisfactory answers to all associated problems. Keeping all these factors into consideration here is an attempt to effect of *Drakshadi Gutika* in the management of *Amlapitta*.

AIM AND OBJECTIVES

1. To study in detail the disease *Urdhwaga Amlapitta*.
2. To study the aetiopathogenesis of *Urdhwaga Amlapitta*.
3. To evaluate the clinical efficacy of *Drakshadi Gutika* in the management of *Urdhwaga Amlapitta*.

MATERIALS AND METHODS

Source of data

- Literary Source:** Literary and conceptual study for the present study was based on the data from Ayurvedic books available from BLDEA's AVS Ayurveda Mahavidyalaya library, and other sources which include magazines, previous work done, research paper's, website etc.
- Drug Source:** The medicines required for the present study were procured from the Pharmacy of BLDEA'S AVS Ayurveda Mahavidyalaya, Vijayapur, Karnataka.
- Clinical Source:** Patients of either sex diagnosed suffering from *Amlapitta* were selected from OPD & IPD of BLDEA's AVS Ayurveda Mahavidyalaya Hospital, Vijayapur.

Method of collection of data

A special proforma was prepared with details of history, physical signs and symptoms mentioned for the *Amlapitta*. Patients were analyzed and selected accordingly. A viable and indigenously designed method was used to assess the parameters of signs and symptoms.

Design of the study

Study Design: Randomized Single Blind Comparative Clinical Study.

Sample Size: Total number of patients taken for the study are 60 excluding dropouts.

Duration of Treatment: 30 days

Duration of Follow-up: 15 days

Study Duration

Total study duration: 30 days

Treatment duration: 30 days

Follow up duration: 15 days

Statistical Analysis

The obtained data was analyzed statistically and presented as mean \pm SEM. The data generated during the study was subjected student's "Unpaired 't' Test" for unpaired data to assess the statistical significance between the two groups. The change in signs and symptoms will be analyzed by Paired 't' test.

Inclusion Criteria

1. Patients of both sexes were selected.
2. Patients of age group between 18-60 yrs.
3. Patients suffering from signs and symptoms of *Urdhwag Amlapitta* i.e., *Avipaka* (Indigestion), *Hrit-Kanthadaha* (Heart burn), *Tiktamla Udgara* (acid eructation), *Utklesa* (Nausea), *Vamana* (Vomiting), *Udarshula* (abdominal pain), *Adhman* (Flatulence), *Klama* (Tiredness), *Aruchi* (Anorexia)
4. Patient from all socio-economic status were taken.

Exclusion Criteria

1. Known Patients having *Nilkrushnarakta Vamana* (bile-blood vomiting), *Murchha* (syncope), *Angapitata* (yellow coloration of body), *Krushnaraktmalasarana* (black and bloodletting stool), *Amashayavrana* (stomach ulcer), *Grahnivrana* (Duodenal ulcer).
2. Patients of *Pittashayasmari* were excluded.
3. Patient with *Adhog Amlapitta* were excluded.
4. Patient having fever more than 100°F were excluded from study
5. Patients below 18 years & above 60 years of age.
6. Patients suffering from acid peptic disorder for more than 3 years.
7. Patient with pregnancy, severe anaemia, heart disease, Known patients of malignancy of G.I.T. were excluded.

Criteria for diagnosis

Diagnosis was made on the basis of *Samanya Lakshanas* of *Amlapitta* viz. *Avipaka* (Indigestion), *Hrit-kanthadaha* (Heart burn), *Tiktamlaudgara* (acid eructation), *Utklesa* (Nausea), *Vamana* (Vomiting), *Udarshula* (abdominal pain), *Adhmana* (Flatulence), *Klama* (Tiredness), *Aruchi* (Anorexia).

Subjective Parameters

1. *Chhardi / Vaanti*
2. *Shiroruja*
3. *Kara-Charan Daha*
4. *Hrid-Kantha Daha*
5. *Tikta-Amlodgar*
6. *Hrullasa*

Similarly other symptoms were also given scores on the basis of this before & after treatment score.

1) Chhardi

Score	Grading of the symptoms
0	No vomiting
1	Nausea & vomiting occasionally.
2	Frequency is not more than 2-3 per week.

3	Frequency of vomiting is between 4- 6 per week.
4	Frequency of vomiting is daily.

2) Tikta-Amlodgar

Score	Grading of the symptoms
0	No <i>Tikta-amlodgar</i> .
1	Sometimes during the day.
2	<i>Tikta-amlodgar</i> within one <i>Annakala</i> .
3	Amount of fluid regurgitate to patient's mouth.
4	Persistent throughout the day & can't perform day to day work.

3) Kantha-Hridaya-Kukshi Daha

Score	Grading of the symptoms
0	No <i>Daha</i>
1	<i>Daha</i> in any area of <i>Udara/Abdomen</i> .
2	<i>Daha</i> in <i>Uro Pradesh</i> with regurgitation.
3	<i>Daha</i> in <i>Kanth Pradesh</i> .
4	<i>Daha</i> relieved by vomiting.

4) Shirashula

Score	Grading of the symptoms
0	No <i>Shirashula</i> .
1	Occasionally <i>Shirashula</i> .
2	Frequency is not more than 2-3 per week.
3	Frequency of <i>Shirashula</i> is between 4- 6 per week.
4	<i>Shirashula</i> relieved after vomiting/ medication.

Agnidushti Symptoms: *Aruchi, Avipak, Agnimandhya*.

SN	Symptoms	Score
1.	<i>Aruchi</i>	2 - if present, 1 - if improvement in the symptoms, 0 - if absent.
2.	<i>Avipak</i>	2 - if present, 1 - if improvement in the symptoms, 0 - if absent.
3.	<i>Agnimandhya</i>	2 - if present, 1 - if improvement in the symptoms, 0 - if absent.

Associated Symptoms: *Klama, Gaurav, Gurukoshtata, Aadhman.*

SN	Symptoms	Score
1.	<i>Klama</i>	2 - if present, 1 - if improvement in the symptoms after, 0 - if absent.
2.	<i>Gaurav</i>	2 - if present, 1 - if improvement in the symptoms after, 0 - if absent.
3.	<i>Gurukoshtata</i>	2 - if present, 1 - if improvement in the symptoms after, 0 - if absent.
4.	<i>Aadhman</i>	2 - if present, 1 - if improvement in the symptoms after, 0 - if absent.

Laboratory investigations

1. Blood Routine for Hb %, TC, DC, ESR.
2. Urine examination for sugar, albumin, and micro-organism.
3. Stool examination for occult blood.

OBSERVATIONS AND RESULTS

Out of 71 patients, 5 patients (7.04%) were with age 18-24years, 14 patients (19.72%) were with age 25-30 years, 12 patients (16.90%) were from age group 31-36 years, 17 patients (23.94%) were from age group 37-42 years, 10 patients (14.08%) were from age group 43-48 years, 4 patients (5.63%) were from age group 49-54years, 9 patients (12.68%) were from age group 55-60 years. Out of 71 patients, 41 patients (57.75%) were male while 30 patients (42.25%) were female. Out of 71 patients, 2 patients (2.81 %) were lower class, 49 patients (69.01 %) were Middle class while 20 patient (28.16) was Upper class. Out of 71 patients, 8 patients (11.26 %) were Active, 16 patients (22.53%) were Sedentary, 42 patients (59.15%) were in Labour while 5 patients (7.04%) were Student. Out of 71 patients, 61 patients (85.91%) were married, 10 patients (14.08%) were unmarried.

Out of 71 patients, 15 patients (21.12%) were with *Kapha - Pitta Prarkuti*, 30 patients (42.25) were with *Pitta-Kapha*, 18 patients (25.35 %) were with *Vata - Kapha Prarkuti*, while 23 patients (32.39%) were with *Vata - Pitta Prarkuti*. Out of 71 patients, 35 patients

(49.30 %) were taking mixed diet while 36 patients (50.70 %) were vegetarian. Out of 71 patients, 29 patients (40.84%) were *Mrudu Kostha*, 24 patients (33.80 %) were *Krura Kostha*, 18 patients (25.35%) were in *Madhyama Kostha*. Out of 71 patients, 33 patients (46.47 %) were *Mandagni*, 17 patients (23.94%) were *Tiksnagni*, 21 patients (29.57%) were in *Vishamagni*. Out of 71 patients, 22 patients (30.98%) were addicted to Alcohol, Tobacco, 15 patients (21.12%) were addicted to Tobacco, 34 patients (47.88%) were consuming Tea in excess quantity. Out of 71 patients, 43 patients (60.56 %) were doing *Vegavidharan*, 28 patients (39.43 %) were doing *Divaswapna*.

Effect of therapy

In the present study total 71 patients were registered, out of which 6 patients have dropped out the treatment, out of remaining 30 patients were treated with *Drakshadi Gutika* (Group A) and 30 patients were treated with *Sutashekhara Rasa* (Group B).

Effect of therapy in Group A

In this group total 36 patients were registered out of which 6 patients were dropped out while remaining 30 patients have completed the full course of treatment. Here the effect of drug *Drakshadi Gutika* on various parameters is presented in the following tables.

Group A	Mean	N	SD	SE	Wilcoxon W	P	% relief	
<i>Avipaka</i>	B T	0.6 7	3 0	0.8 8	0.1 6	-2.919 ^a	0.00 4	65. 0
	A T	0.2 3	3 0	0.4 3	0.0 8			
<i>Hrita Kantha Daha</i>	B T	0.9 3	3 0	0.9 4	0.1 7	-3.666 ^a	0.00 0	75. 0
	A T	0.2 3	3 0	0.5 0	0.0 9			
<i>Tikta Amla Udgara</i>	B T	1.3 7	3 0	1.1 9	0.2 2	-3.729 ^a	0.00 0	63. 4
	A T	0.5 0	3 0	0.5 7	0.1 0			

Utklesha	B	1.9	3	0.9	0.1	-4.817 ^a	0.00	50.8
	T	7	0	3	7			
Vamana	A	0.9	3	0.7	0.1	-2.251 ^a	0.02	64.3
	T	7	0	2	3			
Udarashula	B	0.4	3	0.8	0.1	-2.428 ^a	0.01	62.5
	T	7	0	6	6			
Adhmana	A	0.1	3	0.4	0.0	-2.251 ^a	0.02	75.0
	T	7	0	6	8			
Klama	B	0.4	3	0.8	0.1	-2.460 ^a	0.01	64.3
	T	7	0	6	6			
Aruchi	A	0.1	3	0.3	0.0	-3.051 ^a	0.00	95.0
	T	0	0	1	6			
Klama	B	0.4	3	0.8	0.1	-2.460 ^a	0.01	64.3
	T	7	0	6	6			
Aruchi	A	0.0	3	0.1	0.0	-3.051 ^a	0.00	95.0
	T	3	0	8	3			

Since observations are on ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test efficacy in Group A. In *Aruchi* 95%, *Hritkanthadaha* 75%, *Adhmana* 75%, *Avipak* 65%, *Klama* 64.3%, *Vamana* 64.3% *Tiktamlodgar* 63.4%, *Udarshoola* 62.5%, *Utklesh* 50.8% relief was recorded. From above table we can observe that P-Values for all parameters are less than 0.05. Hence, we conclude that effect observed in Group A is significant.

Effect of therapy in Group B

Group B	Mean	N	SD	SE	Wilcoxon W	P	% relief
Avipaka	B	0.4	3	0.8	-2.271 ^a	0.02	57.1
	T	7	0	6			
Aruchi	A	0.2	3	0.4	-2.271 ^a	0.02	57.1
	T	0	0	8			

Hritkanthadaha	B	0.5	3	0.5	0.1	-3.606 ^a	0.00	81.3
	T	3	0	7	0			
Tikta Amla Udgara	A	0.1	3	0.3	0.0	-3.900 ^a	0.00	53.1
	T	0	0	1	6			
Utklesha	B	1.0	3	0.7	0.1	-3.606 ^a	0.00	48.1
	T	7	0	8	4			
Vamana	A	0.5	3	0.5	0.1	-3.963 ^a	0.00	57.8
	T	0	0	7	0			
Udarashula	B	1.5	3	1.1	0.2	-4.326 ^a	0.00	60.7
	T	0	0	1	0			
Adhmana	A	0.6	3	0.6	0.1	-2.598	0.00	72.2
	T	3	0	7	2			
Klama	B	0.6	3	0.9	0.1	-2.585	0.01	66.7
	T	0	0	3	7			
Aruchi	A	0.2	3	0.4	0.0	-2.739	0.00	70.0
	T	0	0	8	9			

Since observations are on ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test efficacy in Group B. In *Aruchi* 70%, *Hritkanthadaha* 81.3%, *Adhmana* 72.2%, *Avipak* 57.1%, *Klama* 66.7%, *Vamana* 57.8% *Tiktamlodgar* 53.1%, *Udarshoola* 60.7%, *Utklesh* 48.1% relief was recorded. From above table we can observe that P-Values for all parameters are less than 0.05. Hence, we conclude that effect observed in Group B is significant.

DISCUSSION

Amlapitta is a psychosomatic disorder either it may be because of *Aharaja*, *Manasika* or *Viharaja Nidana*. So, in the present study we selected *Drakshadi Gutika* and *Laghu Sutashekhar Rasa* to see the effect of both drugs in the patients. *Mandagni* is the main cause for all the disease, this *Mandagni* causes *Avipaka*, it turns in to *Shukta Paka* acts like *Amavisha* which is nothing but *Ama*, this *Ama* vitiates *Annavaha Srotases* produces the symptoms like *Aruchi*, *Agnimandhya*, *Vamana*, these are the factors which are involved in the manifestation of the disease *Amlapitta*.

In the present study *Drakshadi Gutika* was used as trail drug to evaluate its efficacy in *Amlapitta*. The ingredients are *Draksha*, *Haritaki* and *Khandsharakara*. The ingredients having the properties like *Katu*, *Tikta*, *Kashaya* and *Madhura Rasa* pacify *Pitta* and *Kapha*. The *Gunas Laghu*, *Ruksha* pacifies *Kapha Dosh*; *Snigdha Guna* help in the digestion by doing *Agnideepana (Kledana)*. *Katu Vipaka* pacifies *Kapha Dosh* and brings back to normal *Rasa* of *Pitta*. *Sheeta Virya* pacifies *Pittadosha* and *Ushnavirya* acts as *Agnideepaka* by increasing its *Teekshna Guna* and does *Kapha Shaman*. Both the drugs *Draksha* and *Haritaki* having *Deepaka* and *Pachaka Karma*. The *Draksha* that is *Sheeta Virya* and *Madhura Vipaka* acts as *Pitta* and *Daha Shamaka*. This *Draksha* when processed with *Deepaka* and *Pachaka Dravyas* acquires the *Deepaka Pachaka* and *Pittashamaka* attributes due to its *Sanskarasyanuvartana* property, So, *Drakshadi Gutika* is one of the best *Aushadhi* for *Amlapitta*.

CONCLUSION

In this study after treatment *Drakshadi Gutika* (Group A) showed significant effect on the symptoms *Avipaka*, *Aruchi* and *Chardi*. And highly significant effect on *Klama*, *Utklesha*, *Hrutkantha Daha*, *Tiktamla Udghara*,

Gourava and *Shirashula*. But in the follow-up period non-significant effect was observed in the symptoms.

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