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# COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF DRAKSHADI GRANULES AND PATOLADI SYRUP IN AMALPITTA W.S.R TO NON ULCER DYSPEPSIA

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### **ABSTRACT**

Ayurveda considers disturbance of *Agni* system as the root cause of all the diseases, particularly related to Gastro-intestinal tract diseases. *Amalpitta* is one of such diseases which occur due to the *Agni Vaikritya* leading to production of *Amma*. *Hurry*, *Worry* and *Curry* are the main attributes of *Amalpitta*. The present study was conducted to explore the potential of an *Ayurvedic* formulations *Drakshadi Grnaules* and *Patoladi Syrup* in the management of *Amlapitta* w.s.r. to Non-Ulcer Dyspepsia. The study was conducted on 30 patients. Investigations were done to rule out any pathology. The subjective criteria included the symptoms: *Hrita Kantha Daha* (Retrosternal burning), *Amlodgara* (Sour eructations), *Utklesha* (Nausea), *Avipaka* (Indigestion) *Chhardi* (Vomiting), *Aruchi* (Loss of appetite), *Kukshi Daha* (Epigastric burning), *Udaradhamana* (Flatulence) and *Klama* (Mental fatigue). Assessment of the patients revealed that therapies given in Group 1 and Group 2 were equally effective. No untoward effect was reported.

KEYWORDS: Amalpitta, Non Ulcer Dyspepsia, Agni, Drakshadi Granules, Patoladi Syrup.

### INTRODUCTION

Dietary habits in present day, changing life style, stress and strain related to job or domestic worries has shown an adverse impact on the normal process of digestion. Amalpitta can be linked to wide spectrum of diseases like Non-ulcer dyspepsia, Acid peptic disorder, Gastroesophageal reflux disease, Acute gastritis, Chronic gastritis, Hyperchlorhydria, Menetrier's disease etc. Functional dyspepsia is defined as a dyspepsia of more than 3 months without an organic cause, It is the cause of symptoms in 60% of patients with dyspeptic symptoms. Dyspepsia is one of the most common gastro-intestinal complaint. Approx. prevalence is: Non Ulcer Dyspepsia-Up to 60%, Dyspepsia caused by structural or biochemical disease-Up to 40%, Gastritis-3.7 million people(1996), Non Ulcer Dyspepsia -6.4 million people(1996)<sup>2</sup>. In India it is approximately 10 million .The change in life style has led to an unprecedented rise in the disorders of gastro-intestinal system. The dietary habits of present day, stress and strain related to job or domestic worries has adverse impact on the normal functioning of Agni. Such individuals are prone to suffer from *Amalpitta*. Non Ulcer Dyspepsia is a hetrogenous syndrome. No single abnormality accounts for all the

symptoms. There are multiple factors which lead to dyspeptic symptoms mainly.

- a) Impaired motor and sensory functions-
- Delayed gastric emptying.
- Intestinal dysmotility.
- b) Mucosal inflammation due to-
- Helicobacter pylori infection.
- Drugs -NSAIDS.
- c) Psycho-social factors-
- Stress
- Anxiety
- d) Dietary habits and Environmental factors

### MATERIAL AND METHODS

- Clinical Study The present study was carried out to evaluate the clinical profile of patient suffering from *Amlapitta* and to assess the effect of an *Ayurvedic* formulations in its management.
- Selection of Study Subjects Study subjects were selected from OPD/IPD of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, Distt. Kangra (H.P.) 176115. A detailed history was obtained and relevant investigations were carried out before the enrolment of individuals in the study.

- **Diagnostic Criteria For** *Amalpitta* A diagnostic criterion was mainly based on the signs and symptoms of *Amalpitta* described in *Ayurvedic* classics such as:
- Avipaka (Indigestion)
- Aruchi (Loss of appetite)
- *Hritkanthadah* (Retrosternal burning)
- Tiktaamlodgara (Sour Eructations)
- *Utklesha* (Nausea)
- Kukshi daha (Epigastric Burning)
- *Udaradhmana* (Flatulence)
- Klama (Mental Fatigue)
- Chardi (Vomiting)

### **Inclusion Criteria**

- Patient who were willing to undergo trial and ready to give written consent.
- Individuals of either gender aged between 20-60 years.
- Patients who were presented with classical features of *Amalpitta*.

#### **Exclusion Criteria**

- Patients who were not willing to undergo the treatment.
- Patients below the age of 20 years and above 60 years
- History of Gastric Ulcer/Surgery.
- Those who were using Aspirin or other NSAIDs.
- Patients who were suffering from Malignancy, Cardiac problems, Tuberculosis, CRF, Diabetes Mellitus
- Alarming symptoms like Weight Loss, GI bleeding and any other serious ailment.

#### **Grouping Of Patients-**

For the present clinical study 30 patients were enrolled and they were randomly divided into following two groups.

Group I: 15 patients were registered in this group and were given *Drakshadi* Granules.

Group II: 15 patients were registered in this group and were given *Patoladi* Syrup.

### **Trial Drugs**

1. Drakshadi Granules- The ingredients of drugs Drakshadi Granules in is as follows.

S.NO	Ingridient	Botanical name	Family	Part used
1	Draksha	Vitis Vinefera	Vitiaceae	Phala
2	Haritaki	Terminalia Chebula	Combretaceae	Percarp of fruit
3	Sharkara			

### Properties of Drakshadi Granules.

S. NO	Ingrident	Rasa	Guna	Veerya	Vipaka	Dosha karma
1	Draksha	Madhura	Guru, Sara, Snigdha	Sheeta	Madhura	Vata Pitta Shamaka
2	Haritaki	Panchrasa	Laghu, Ruksha	Ushna	Madhura	Tridoshahara

2. Patoladi Syrup - The ingredients and proportion of drugs in Patoladi Syrup is as follows.

S.NO	Ingridient	Botanical name	Family	Part used
1	Patola	Trichosanthes diocea	Cucurbitaceae	Panchang
2	Pippali	Piper longum	Piperaceae	Phala
3	Yava	Hordeum vulgare	Poaceae	Phala
4	Sita			

## Properties of Patoladi Syrup.

S. NO	Ingrident	Rasa	Guna	Veerya	Vipaka	Dosha karma
1	Patola	Tikta	Laghu, Snigdha	Ushna	Katu	Tridosh Shamaka (Mainly Pitta Shamak)
2	Pippali	Katu	Laghu, Snigdha, Tikshna	Anushna Sheeta	Madhura	Vata Kapha Shamaka
3	Yava	Kashaya Madhura	Ruksha, Guru, Picchila, Mridu	Sheeta	Katu	Kapha Pitta Shamaka

### Drug Dosage

o Drakshadi Granules

Patoladi Svrup

• Route of Administration

Duration of treatment

• Anupana

- 5 gms twice a day
- 20 ml twice a day
- Oral
- 30 days
- Water

**Follow up** – First follow up was done on 15 day and second at the completion of trial. After starting the therapy, the patients were examined in every visit for pulse, blood pressure, temperature, signs and symptoms, appetite, bowel habits, and general condition. After 30 days, when the trial was completed, thorough examination of the patient was carried out. The patients

who were failed to continue the therapy for whole duration were considered drop out.

### Criteria of Assessment

Scoring system was adopted for assessment of various subjective features and grades from zero to four were recorded to various features according to the severity.

## Grading

1. Hritkantha Daha (Retrosternal burning)	
• No Daha	0
• Daha of mild degree	1
• Daha of moderate degree relieved by cold milk, drinks, antacids, food and vomiting.	2
<ul> <li>Daha of severe degree involving Hrith Kantha Daha etc. and relieved after digestion of food or vomiting</li> <li>Daha of severe degree not relieved by any measure mentioned above</li> </ul>	3 4
2. Amla-Udgara (Sour eructations)	
• No Amla-Udgara at all	0
Occasional Amla-Udgara during day  Amla Udgara of moderate soverity.	1
<ul> <li>Amla-Udgara of moderate severity</li> <li>Severe Amla-Udgara disturbing the patients daily routine</li> </ul>	2 3
Small amount of fluid regurgigates	4
3. Utklesha (Nausea)	
• Absent	0
Occasional desire to vomit	1
<ul> <li>Frequent desire to vomit</li> <li>Continuous desire to vomit</li> </ul>	2 3
<ul> <li>Continuous desire to voinit</li> <li>Continuous desire to voinit with profuse water brash</li> </ul>	3
•	•
4. Avipaka (Indigestion)	0
<ul><li>Normal digestion</li><li>Indigestion 2-3 times a week</li></ul>	0 1
Occurs daily but not severe	2
<ul> <li>More than 2-3 times Ajirna Ahara Lakshans like Guruta Gland</li> </ul>	
Severe indigestion which does not subside without medicine	4
and Langhana	
5. Chhardi (Vomiting)	
No vomiting	0
• Feels sense of nausea and vomits occasionally	1
<ul> <li>Frequency is not more than 2-3 per week</li> <li>Frequency of vomiting between four to six per week-</li> </ul>	2 3
and increases when pain is aggravated	3
• Frequency of vomiting daily after every meal-	4
6. Aruchi (Loss of appetite)	
Normal desire for food	0
• Eating timely without much desire	1
• Unable to take even desired food	2
<ul> <li>Smell and presence of food causes aversion</li> <li>No desire for food at all</li> </ul>	3
No desire for food at all	4

## 7. Udar Adhman (Flatulence)

•	Absent	0
•	Occasional feeling of distension or gaseousness in abdomen	1
•	Moderate complaint or discomfort	2
•	Frequently distended abdomen	3
•	Continuous flatulence in abdomen	4

# 8. Klama (Mental fatigue)

•	No complaint	0
•	Mild stress with occasional headache	1
•	Moderate stress	2
•	Severe stress with heaviness in head, relieved by vomiting	3
•	Continuous heaviness in head, not relived by vomiting	4

# 9. Kuksi Daha (Epigastric Burning)

•	Absent	0
•	Occasional burning sensation in abdomen	1
•	Burning sensation 3-4 times a day relieved by water and food	2
•	Continuous complaint relieved by Antacids	3
•	Continuous complaint not relieved by Antacids	4

Statistical Evaluation And Result Analysis - Analysis of data was done after entering into excel sheets. To draw conclusion statistical derivations were constructed. Tables and charts were made to signify the important findings. Paired't' test was used for the statistical assessment. And it was also used for the intergroup statistical analysis. The results were expressed in terms of Mean, Standard Deviation (S.D) and Standard Error (S.E). The results were considered significant or insignificant depending upon the value of 'p':-

•	Highly significant	-	p<0.001
•	Significant	-	p<0.05-0.01
•	Insignificant	_	p > 0.05

Status	Study subjects
Completed the treatment	27
Dropped out	3
Total	30

## Demographic Data

Observations	No. of Patients / Percentage/ Maximum incidence
Age	11 patients / 36.66% / 41-50 years
Sex	20 patients / 66.66% / Female
Marital status	27 patients / 90% / Married
Religion	All patient / 100% / Hindu
Habitat	20 patients / 66.66% / Rural
Education	10 patients / 33.33% / Illiterate
Occupation	21 patients / 70% / Housewife
Socio economic Status	17 patients / 56.66% / Middle class
Dietary Habits	18 patients / 60% / Mixed diet
Use of Spices and chillies	17 patients / 56.66%
Addiction	17 patients / 56.66% / Tea
Bowel Habits	19 patients / 63.33% / Irregular
Appetite	18 patients / 60% / Reduced
Timing of Food Intake	22 patients / 73.33% / Not Fixed and Irregular

Life style	14 patients / 46.66% / Active
Sleep	22 patients / 73.33% / Normal sleep
Chronicity	16 patients / 53.33% / 2 months to 2 years
Prakriti	13 patients / 43.33% / Vatapitaja
Satva	18 patients / 60% / Madhyama
Abhyarana Shakti	17 patients / 56.66% / Madhyama
Jarana Shakti	18 patients / 60% / Heena Jarana Shakti
Satmya	18 patients / 60% / Vyamishra Satmya
Koshtha	17 patients / 56.66% / Krura koshtha
Vyayma	17 patients / 56.66% / Heena Vyayma Shakti

# Effect of therapy on Hrita Kantha Daha in the patients of Amalpitta.

Groups N		Mean score		% age	SD±	SE <u>+</u>	't'	ʻp'	Intergroup
Groups	11	BT	AT	change	3D <u>∓</u>	<u> 512π</u>	value	value	comparison
I	12	2.58	0.42	83.7	0.72	0.207	10.45	< 0.001	t = 0.094
П	13	2.62	0.54	79.31	0.49	0.136	15.17	< 0.001	p > 0.05

## Effect of therapy on Amlodgara in the patients of Amalpitta.

Стопта	N	Mean score		% age	SD <u>+</u>	SE+	't'	ʻp'	Intergroup
Groups	11	BT	AT	change	SD <u>+</u>	SE <u>#</u>	value	value	comparison
I	13	2.69	0.46	82.8	0.59	0.166	13.42	< 0.001	t = 0.277
II	13	2.46	0.46	81.3	0.41	0.113	17.66	< 0.001	p >0.05

# Effect of therapy on Utklesha in the patients of Amalpitta.

Groups	N	Mean score		% age	SD	SE±	't'	<b>'p'</b>	Intergroup
	11	BT	AT	change	SD <u>+</u>	SE <u>∓</u>	value	value	comparison
I	10	2.10	1.0	52.3	0.74	0.233	4.71	< 0.01	t = 0.278
II	09	2.5	1.25	50.1	0.71	0.25	5.00	< 0.01	p > 0.05

## Effect of therapy on Avipaka in the patients of Amalpitta.

Смочью	N	Mean score		% age	SD+	SE.	't'	ʻp'	Intergroup
Groups	11	BT	AT	change	SD <u>+</u>	SE <u>+</u>	value	value	comparison
I	10	2.7	0.60	77.7	0.74	0.233	9.00	< 0.001	t = 0.421
П	13	2.38	0.62	73.94	0.59	0.166	10.64	< 0.001	p > 0.05

# Effect of the rapy on Chhardi in the patients of Amalpitta.

Groups N				% age	SD±	SE+	't'	<b>'p'</b>	Intergroup
Groups	IN	BT	AT	change	SD <u>+</u>	Э <u>г</u>	value	value	comparison
I	07	2.0	0	100	0.57	0.218	9.16	< 0.001	t = 0
II	13	2.0	0	100	0.82	0.258	7.74	< 0.001	p > 0.05

## Effect of therapy on Aruchi in the patients of Amalpitta.

Groups	N	Mean score		% age	SD+	SE+	't'	'p'	Intergroup
Groups	11	BT	AT	change	3D <u>+</u>	3E <u>#</u>	value	value	comparison
I	12	2.08	0.25	87.98	1.11	0.321	5.69	< 0.001	t = 0.094
II	12	2.25	0.50	77.77	0.62	0.179	9.75	< 0.001	p > 0.05

Effect of therapy on kukshi Daha in the patients of Amalpitta.

Groups	N	Mean score		% age	SD:	SE±	't'	'p'	Intergroup
		BT	AT	change	SD±	ЭĽ <u>т</u>	value	value	comparison
I	14	2.71	0.43	84.13	0.61	0.163	13.9	< 0.001	t = 0.154
II	13	2.53	0.38	84.88	0.55	0.153	14	< 0.001	p > 0.05

Effect of therapy on *Udardhamana* in the patients of *Amalpitta*.

Cwarma	NI	Mean score		% age	SD.	SE+	't'	ʻp'	Intergroup
Groups	IN.	BT	AT	change	SD±	3E <u>#</u>	value	value	comparison
I	10	2.30	0.60	82.6	0.82	0.260	6.53	< 0.001	t = 0.172
П	12	2.16	0.58	73.14	0.51	0.148	10.65	< 0.001	p > 0.05

Effect of therapy on Klama in the patients of Amalpitta.

Channe	N	Mean score		% age	SD.	SE±	't'	<b>'p'</b>	Intergroup
Groups	11	BT	AT	change	SD <u>+</u>	SE <u>∓</u>	value	value	comparison
I	12	2.16	1.66	38.14	0.95	0.275	3.63	< 0.01	t = 0.388
П	13	2.07	1.21	41.5	0.86	0.231	3.70	< 0.01	p > 0.05

#### DISCUSSION

Amalpitta is the most common problem of society due to changing in life style, diet habits and behavioural pattern. Non Ulcer Dyspepsia is associated with a reduced sense of physical and mental well-being and is exacerbated by stress, suggesting an important role for psychological factors.<sup>3</sup> The irresistible stress and strain of this present era are related with the pathogenesis of this disease. If we see the pathophysiology of the *Amalpitta* states it is more caused due to functional disturbance rather than organic lesion. Amalpitta is a condition where excessive secretion of Amla Guna of Pitta takes place. It is the disease of Annavaha Srotas caused due to Mandagini and Annavaha Srotodushti Some patients with functional dyspepsia complain of specific food intolerance. Coffee acts as a direct irritant, stimulates acid secretion and precipitates gastro esophageal reflex. According to a study conducted at institute of Mental health, women are twice as likely as men to have depression and stress disorders. They are sensitive, anxious, emotional and overthink leading to continuous production of HCl.<sup>5</sup> Commonly overlooked as a cause of dyspepsia is lactose malabsorption, which may cause bloating, cramps, flatulence and diarrhoea. 6 Grade Score method was adopted to evaluate the effect of therapy in both the groups. After completion of 1 month, it was observed that statistically highly significant (p<0.001) results were obtained in Hrita-Kantha Daha, Amlodgara, Avipaka, Chhardi, Aruchi, Kukshi-Daha, Udaradhmana, Klama in both groups.In *Utklesha and Klama*, effect of therapy was statistically significant in both groups. (p<0.01).Inter group comparison showed statistically insignificant difference between the therapies given in trial. (p >0.05).

1. Hrit Kantha Daha: After 1 month, the clinical study showed 83.7% relief in group I and 79.31% relief in group II in Hrita-Kantha Daha. Results were statistically highly significant (p<0.001) in both groups. This may be due to the Sheeta Veerya of Drkasha and Yava and Madhura Vipaka of</p>

Draksha, Haritaki and Pippla which are responsible for Pitta Shamana..

- 2. Amlodgara: After one month, the clinical study showed that 82.8% relief was observed in group 1 and 81.3% relief was observed in group II. This data suggests statistically highly significant results in both the groups.
- 3. *Utklesha*:- After one month, the clinical study showed that 52.3% relief was observed in group I and 50.1% relief was observed in group II. This data suggests statistically significant results in both the groups. Due to the *Katu Rasa* of the *Pippali* and *Haritaki*, it may absorb the increased *Drava Guna* of vitiated *Pachak Pitta*.
- 4. Avipaka After completion of treatment 77.7% relief was observed in group 1 and 73.94% relief for group II. Result shows statistically highly significant results in both groups. Tikta Rasa of Patola and Haritaki having Laghu Guna is Pitta kapha Shamka and helps in Amapachana and Deepana. Whereas Katu Vipaka of Patola and Yava causes Agni Deepna and Amapachana and relieves the symptom Avipaka.
- 5. Chhardi In this symptom 100% relief was observed in both group 1 and group II. Data shows statistically highly significant results in both groups. Due to the katu rasa of the Pippali and Haritaki, it may absorb the increased Drava Guna of vitiated Pachak Pitta.
- **6.** *Aruchi* 87.98% relief was recorded in group 1 after completion of treatment. In group II percentage of relief was 77.77%. The data shows statistically highly significant results in both the groups. It may be due to the *Tikta Rasa* of *Patola* and *Haritaki* having properties like *Deepana* , *Pachana* and Rochana and is said to be *Aruchighana*.
- 7. **Kukshi Daha** After completion of treatment 84.13% relief was observed in group 1 and 84.88% relief in group II Result shows statistically highly significant results in both groups. Relief in *Kukshi*

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- Daha may be due to the Sheeta Veerya of the Draksha and Yava. Madhura Vipaka of Draksha, Haritaki and Pippali which are having Pitta Shamaka effect.
- 8. Udaradhmana 82.6% relief was recorded in group 1 after completion of treatment. In group II percentage of relief was 73.14%. The data shows statistically highly significant results in both the groups. Udaradhmana symptom occurs due to the increased Amla and Drava Guna of vitiated Pachaka Pitta, which may be treated by the Deepana and Pachana properties of Patola and Haritaki. Also Madhura Viapka of Draksha, Hritaki and Pippali is having Srishta Vidmootra property which leads to Vatanulomna.
- 9. *Klama*:- 38.14% relief was recorded in group 1 after completion of treatment. In group II percentage of relief was 41.5%. The data shows statistically significant results in both the groups .It is due to the vitiation of *Vata*, hence *Madhura Rasa* of *Draksha*, *Haritaki* and *Yava*. *Ushana Veerya* of *Haritaki* and *Patola* are responsible for *Vata Shamana*.

#### CONCLUSION

Assessment of the patients revealed that therapies given in Group 1 and Group 2 were equally effective over symptoms like *Hrita Kantha Daha*, *Amlodgara*, *Utklesha*, *Chhardi*, *Kukshi Daha*, *Avipaka*, *Aruchi And Udardhamana*. Intergroup comparison showed statistically insignificant difference between the therapies given. Trial drugs *Drakshadi Granules* and *Patoladi Syrup* are well tolerated by the patients and no untoward effect was reported.

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