

“A CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF TRIVRITADI YOGA IN AMLAPITTA”

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ABSTRACT

Background: Amlapitta is one of the commonest ailment found in the present era of civilization. Unhealthy food habits, work stress, anxiety, improper sleep etc has contributed to disturbances in digestive system. Faulty dietary habits produces *Jataragni dushti* which leads to the formation of *Sama Pitta* which ultimately leads to the formation of *Shuktapaka* and manifest as *Amlapitta*. **Objectives of the study:** To evaluate the therapeutic effect of *Trivritadi yoga* granules in *Amlapitta*. **Methodology:** 30 subjects suffering from *Amlapitta* were selected for the study, based on the diagnostic, inclusion and exclusion criteria from OPD and IPD of SDM Ayurveda hospital, Udupi. *Trivritadi yoga* granules were administered in a dose of 12 gm in the morning after food with lukewarm water for a duration of 30 days. *Trivritadi yoga*

granules were obtained from Sri Dharmasthala Manjunatheswara Ayurveda Pharmacy, Udupi. **Results:** The study showed remarkable and statistically significant results.

Conclusion: The study had a positive outcome and can be recommended in patients suffering from *Amlapitta*.

KEYWORDS: *Amlapitta*, *Trivritadi yoga* granules, *Shamanoushadi*.

INTRODUCTION

Amlapitta is one of the commonest *Jataragnimandhya Janya Vyadhi*, which leads to *vidagdha jeerna* by the simultaneous vitiation of the three *doshas*.^[1]

Due to various factors in the present era of civilization like rapid environmental changes, adaptation of newer & newer food items and dishes, changes in cooking methods etc. have precipitated the increasing trend of the diseases. Along with these stimulating factors tremendous stress, strain, disturbed sleep & anxiety have significantly contributed to the diseases including *Amlapitta*. Besides, addictions like smoking, alcohol, tobacco chewing, excessive stress, drugs like NSAID's, corticosteroids also contribute to *Amlapitta*.

Indulging in *Ajirna*, *Atibhojana*, *Vishama Bhojana*, *Asatmya* and *Sandushta Bhojana* produces *Shuktata*^[2] due to *Jataragni dushti* simultaneously leading to *rasa dhatu dushti*, formation of *Ama* and ultimately leading to formation of *Amlaroopi Pitta*. In the individuals where *Pitta Dosha* is already in *Chaya Avastha*, intake of *Vidahi*, *Amla Ahara* leads to *Amlapaka* and *Vidagdha Ajeerna*, thereafter manifestation of the disease *Amlapitta*.^[3] This causes vitiation of the whole *Annavaha srotas*. Main *lakshana* of *Amlapitta* are given as *Avipaka*, *Klama*, *Utklesha*, *Tikta Amlodgara*, *Gourava*, *Hrith kanta daha* and *Aruchi*.^[4]

Elaborate description of *Amlapitta* as a disease is available in *Kashyapa Samhita*.^[5]

Indications about adopting *Chikitsa* of *Rakthapitta* and *Shula* as well in *Amlapitta* can be seen in classics.^[6] *Trivritadi yoga* is explained in *Rakthapitta adhikara*.^[7]

The ingredients of *Trivritadi yoga* are *Trivrit*, *Triphala*, *Sariva*, *Pippali* and *Sarkara*. Even though *Amlapitta* is a non-dreadfull disease, it hampers day to day activities of the patient. Long term use of antacids and acid-suppressing agents leads to adverse effects like hypersensitivity, alkalosis, calculi, constipation, etc.^[8,9] Many preparations are available in classics, but the action of drug in different condition of the disease with respect to dominance of *Dosha* and types, according to direction *Urdhwaga* and *Adhoga*, chronicity and severity of disease is not explained in detail. Keeping all these in consideration a clinical study was conducted to evaluate the therapeutic effect of *Trivritadi yoga* in *Amlapitta*.

METHODOLOGY

Ethical committee clearance has been done Reference number. SDMCAU/ACA-49/ECH 12/2020-21

Objectives of the study

To evaluate the therapeutic effect of *Trivritadi yoga* in *Amlapitta*.

Study design

- ☉ Study Type : Interventional
- ☉ Estimated enrolment : 30 participants
- ☉ Allocation : Non randomized
- ☉ Endpoint Classification : Efficacy study
- ☉ Intervention Model : Single group assignment
- ☉ Masking : Open label study
- ☉ Primary Purpose : Treatment

Setting: Sri Dharmasthala Manjunatheshwara Ayurveda Hospital Kuthpady, Udupi.

Participants: 30 patients diagnosed with *Amlapitta* were taken for the study. Drugs required for the study were procured from S.D.M Ayurveda Pharmacy, Udupi.

Intervention

Medicine - *Trivritadi yoga* granules

Dose - 12 gm once a day in the morning

Anupana - *Shritasheetta jala*

Time of administration- After food

Duration of study – 30 days

Follow up: Follow up was done on 15th and 30th day of treatment.

DIAGNOSTIC CRITERIA

☉ Clinical diagnosis was made on the basis of *Samanya Lakshana* of *Amlapitta* such as *Tikta Amlodgara, Hrit kanta daha, Avipaka*.

INCLUSION CRITERIA

- ❖ Patients fulfilling the diagnostic criteria
- ❖ Patients between age group 18- 60 years
- ❖ Chronicity less than 5 years

EXCLUSION CRITERIA

- ❖ Pregnant women and lactating mother.

- ❖ Patients with history of systemic illness like Diabetes mellitus and Hypertension, Hyper thyroidism, Cardiac diseases or other chronic systemic illnesses.
- ❖ Patients with history of *Parinama Shula* (duodenal ulcer), *Annadrava Shula* (gastric ulcer), Ca Stomach etc.

ASSESSMENT CRITERIA

Primary Outcome Measures

- ☉ Subjective parameters were assessed before (Day 0) and after treatment (Day 30) and statistically analysed using Wilcoxon's sign rank test.

Subjective parameters

- 1) *Avipaka* 7) *Hrit kanta daha*
- 2) *Gourava* 8) *Vibandha*
- 3) *Utklesha* 9) *Shiroruja*
- 4) *Tikta Amlodgara*
- 5) *Gurukoshtatha*
- 6) *Aruchi*

The parameters were assessed using Amlapitta rating scale with gradings 0 to 3.

The results were statistically analysed using Wilcoxon's sign rank test.

Table No. 1: Assessment Criteria of Amlapitta.

1) Avipaka (Indigestion)	Grade
No indigestion	0
Indigestion only by heavy food	1
Delayed digestion of lighter food	2
Impaired digestion of even lighter food	3
2) Gourava (lethargy)	
No lethargy	0
Occasional but can do daily work.	1
Continuous tiredness that hampers daily work	2
Due to tiredness avoid any routine work	3
3) Utklesha (Nausea)	
No salivation	0
Occasional but not daily	1
Daily for some time after taking solid food	2
Frequently and feel amlata	3
4) Tikta Amla Udgara (acid eructation, belching)	
No Tikta Amlodgara	0
Appears 1-5 times/day only on consumption of sour and spicy food	1

Appears 6-10 times/day on the consumption of any type of food	2
Appears 10 times/day on the consumption of any type of food	3
5) Gurukoshtatha (Heaviness in abdomen)	
No Gurukoshtatha	0
Occasional with normal quantity of food	1
Continuous while taking normal food with an average quantity of food	2
Continuous even while taking less food	3
6)Aruchi (Anorexia)	
No Aruchi	0
Patient feels Aruchi but takes food time to time	1
Patient sometimes take food and sometimes avoid it	2
Patient avoids the food many times	3
7)Hrit kanta daha (Burning sensation)	
No burning sensation	0
Burning sensation after intake of spicy food	1
Feeling of burning sensation even after intake of normal food	2
Burning sensation even in empty stomach	3
8) Vibandha (constipation)	
No constipation	0
Intermittent, relieved by Pathya Ahara vihara	1
Continuous relieved by mild laxative(Mridu Virechana)	2
Continuous, only relieved by strong medication(Teekshna Virechana)	3
8) Shiroruja (Headache)	
No Headache	0
Intermittent, relieved by Pathya Ahara, Vihara	1
Continuous not relieved by Pathya Ahara	2
Continuous, only relieved by medicine	3
9)Other symptoms	
No symptom	0
Mild	1
Moderate	2
Severe	3

OBSERVATIONS

In the present study among 30 patients of Amlapitta it was observed that- 73.3% patients fall under 51-60 age group, 53.3% were males and 46.6% were females, 80% patients were from Rural habitat 73.3% from Anupa Desha. 70% patients were following Veg diet, 73.3% were following Katu-Amla Rasa Pradhana Ahara, 80% patients were following Guru Snigdha Guna Ahara, 73.3% patients were following irregular pattern of food timings, 63.3% patients were following Vishamashana 63.3% had moderate appetite, 53.3% had Vishamagni 60% patients had Krura koshta. 56.6% patients had regular bowel habits, 40% patients had

disturbed sleep, 60% patients had habit of Tea intake, 23.3% patients were anxious and 16.6% were having depressed emotional status.

Among 30 patients, all patients (100%) were having Avipaka, all patients (100%) had Tiktaamlodgara all patients (100%) had Hrit kanta daha, 13 patients (43.3%) had Adhmana, 11 patients (36.6%) had Vibandha 8 patients (26.6%) had Aruchi 8 patients (26.6%) had Shiroruja 6 patients (20%) had Gourava 6 patients (20%) had Utklesha 6 patients (20%) had Guru koshtatha, 4 patients (13.3%) had Urodaha 3 patients (10%) had Udaradaha, 2 patients (6.66%) had Chardi and 1 patient (3.33%) had Hrit shoola.

RESULTS

Table No. 2: Effect of *Trivritadi* yoga granules on *Avipaka*.

	MEAN			Wilcoxon's Signed Rank test				
AVIPAKA	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	2.433	1.7	70.8%	0.679	0.124	3	-4.893	< 0.001
AT	0.733			0.521	0.095	1		

Table No. 3: Effect of *Trivritadi* yoga granules on *Gourava*.

	MEAN			Wilcoxon's Signed Rank test				
GOURAVA	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	0.467	0.367	78.5%	1.008	0.184	0	-2.333	0.031
AT	0.1000			0.0557	0.0557	0		

Table No. 4: Effect of *Trivritadi* yoga granules on *Utklesha*.

	MEAN			Wilcoxon's Signed Rank test				
UTKLESHA	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	2.733	1.766	64.6%	0.640	0.117	3.000	-5.058	<0.001
AT	0.967			0.490	0.0895	1.000		

Table No. 5: Effect of *Trivritadi* yoga granules on *Tikta-Amlodgara*.

	MEAN			Wilcoxon's Signed Rank test				
TIKTA AMLODGARA	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	2.767	1.8	66%	0.504	0.0920	1	-5.108	<0.001
AT	0.967			0.490	0.0895	0		

Table No. 6: Effect of *Trivritadi yoga* granules on *Gurukoshtatha*.

GURU KOSHTATHA	MEAN		% of relief	Wilcoxon's Signed Rank test				
	Mean	Mean difference		SD	SE	Median	Z value	P value
BT	0.600	0.333	55.5 %	1.070	0.195	0	-	0.008
AT	0.267			0.583	0.106	0	2.640	

Table No. 7: Effect of *Trivritadi yoga* granules on *Aruchi*.

ARUCHI	MEAN		% of relief	Wilcoxon's Signed Rank test				
	Mean	Mean difference		SD	SE	Median	Z value	P value
BT	2.100	1.5	71.4%	1.242	0.227	3.000	-4.283	<0.001
AT	0.600			0.675	0.123	0.500		

Table No. 8: Effect of *Trivritadi yoga* granules on *Hrit kanta daha*.

HRIT KANTA DAHA	MEAN		% of relief	Wilcoxon's Signed Rank test				
	Mean	Mean difference		SD	SE	Median	Z value	P value
BT	2.567	1.834	71.4 %	0.568	0.104	1	-	<0.001
AT	0.733			0.640	0.117	0	4.879	

Table No. 9: Effect of *Trivritadi yoga* granules on *Vibandha*.

VIBANDHA	MEAN		% of relief	Wilcoxon's Signed Rank test				
	Mean	Mean difference		SD	SE	Median	Z value	P value
BT	0.567	0.434	76.5%	0.935	0.171	0	-	=0.008
AT	0.133			0.346	0.0631	0	2.565	

Table No. 10: Effect of *Trivritadi yoga* granules on *Shiroruja*.

SHIRORUJA	MEAN		% of relief	Wilcoxon's Signed Rank test				
	Mean	Mean difference		SD	SE	Median	Z value	P value
BT	1.167	0.934	80 %	1.367	0.250	0	-	<0.001
AT	0.233			0.504	0.0920	0	3.337	

Table No. 11: Effect of *Trivritadi yoga* granules on *Adhmana*.

ADHMANA	MEAN		% of relief	Wilcoxon's Signed Rank test				
	Mean	Mean difference		SD	SE	Median	Z value	P value
BT	0.533	0.366	68.66%	1.137	0.208	0	-	0.031
AT	0.167			0.461	0.0842	0	2.232	

Table No. 12: Effect of *Trivritadi* yoga granules on *Chardi*, *Udaradaha*, *Hrit shoola*, *Urodaha*.

	Mean		Mean difference	% of relief
	BT	AT		
CHARDI	0.133	0.066	0.067	50.3%
UDARADAHA	0.233	0.100	0.133	57.08%
HRIT SHOOLA	0.033	0.00	0.033	100%
URODAHA	0.33	0.066	0.264	80%

Overall effect of treatment

- Overall effect of treatment was estimated by analysing the effect of intervention in every subjects. Later they were categorised into Mild improvement 0-25%, Moderate improvement 25-50%, Good improvement 50-75%, Excellent improvement 75-100%.
- Among 30 patients, 56.6% patients got excellent improvement, 40% patients got good improvement and 3.3% patients got moderate improvement from the clinical symptoms.

Table No. 13: Overall effect of treatment.

	Grading	No. of patients	Percentage
EXCELLENT	75-100%	17	56.6%
GOOD	50-75%	12	40%
MODERATE	25-50%	1	3.33%
MILD	0-25%	0	0%

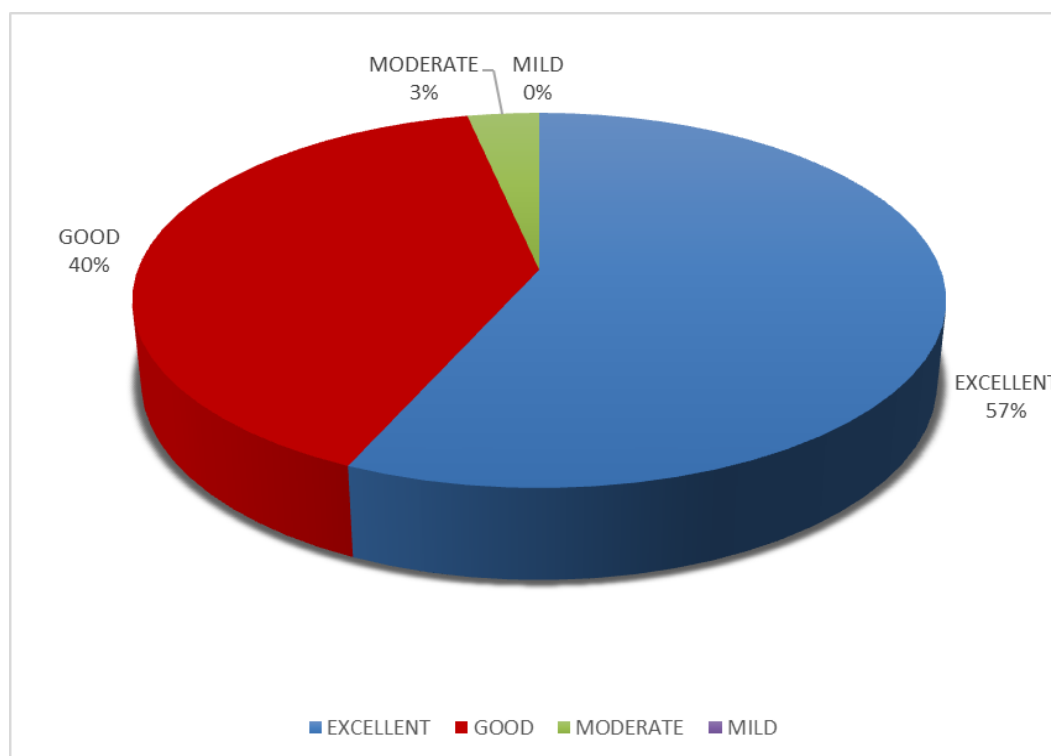


Figure No.1: Overall effect of treatment.

DISCUSSION

The pharmacology of the drug can be understood based on its *Vyadhipratyanikatva* as well as *Doshapratyanikatva* action. *Trivritadi yoga* is explained in *Raktapitta adhikara*. From this it is clear that due to the similarity in pathology of *Raktapitta* and *Amlapitta* it is indicated. In both the diseases *Drava Guna* of *Pitta* is increased and in *Raktapitta*, *Teekshna Guna* is increased and in *Amlapitta* *Amla Guna* is increased.

When we analyse the ingredients of this formulation, it is evident that maximum drugs are having *Tikta Rasa*, which are having *Deepana*, *Pachana Karma* so that it subsides *Pitta* and *Kapha Dosha* in contrast to *Katu Rasa*. The necessary properties in *Amlapitta Chikitsa* like *Laghu*, *Ruksha*, *Sheeta* are also attributed.

Probable mode of action

Trivritadi yoga granules contains *Trivrit*, *Hareetaki*, *Amalaki*, *Vibhitaki*, *Sariva*, *Pippali* and *Sarkara*. *Deepana*, *Pachana* properties seen in drugs like *Pippali*, *Trivrit* etc acts at the level of *Agni* and does *Ama Pachana*, thus reducing the *Vikrita Kapha* produced due to impairment of *Agni*.

Trivrit is having properties like *Katu*, *Tikta Rasa*, *Laghu*, *Ruksha*, *Teekshna Guna*, *Katu Vipaka*, *Ushna Virya*, and *Prabhava* of *Rechana*. Its *Kaphapittahara* and *Vatahara* property makes it an ideal drug in *Amlapitta* which corrects the excess accumulated *Pitta* thereby regulating the gastric acid and brings the *Samana Vayu* into normalcy. The plant root contains a glycoside resin, which is mainly concentrated in the root bark. Studies conducted with Methanolic and Hydroalcoholic extract of *Operculina turpethum* stem bark showed a significant reduction in the total acidity, free acidity, total acid output, and gastric volume. The result suggested that both extracts possess enhanced ulcer preventive and protective activities when compared to the standard drug ranitidine.

Triphala includes the three fruits *Hareetaki*, *Amalaki* and *Vibhitaki*. *Hareetaki* is having *Lavana Varjitha Pancha Rasa*, *Laghu Ruksha Guna*, *Madhura Vipaka* and *Ushna Virya*. It is *Anulomana*, helps to remove *Vibandha* and *Adhmana*. It is *Pitta Kaphahara* due to its *Madhura*, *Tikta*, *Kashaya Rasa*. It is *Vatahara* due to *Katu*, *Tikta*, *Kashaya* and *Amla Rasa*. Studies showed *T. chebula* significantly decreases overall gastric lesions and gastric juice volume while increasing gastric PH and mucus release in different physical and chemical stress-induced ulcer models. Different extracts of *T. chebula* like chloroform extract due to

the presence of carbohydrates, glycosides, triterpenoids, saponins, tannins, polyphenols, proteins, amino acids and flavonoids showed positive results against ethanol-induced gastrointestinal injury in Wistar albino rats and albino mice. The antiulcerogenic action of *T. chebula* was Balanced with a protective impact upon the gastrointestinal mucosa and the improvement in the secretory condition of Brunner's glands. Treatment with *T. chebula* either may eradicate *Pylori* or increase the secretory status of the Brunner's gland, or by inhibiting its attachment by increasing surface hydrophobicity or upregulating mucin secretion, and inhibiting proton pump or solid inhibitory activity against Interleukin-8 secretion, suggesting gastrointestinal protection against *H. Pylori*.

Vibheetaki is having *Kashaya rasa*, *Laghu Ruksha Guna*, *Ushna Virya*, *Madhura Vipaka*. It is having *Kapha Pittahara* property which helps in pacifying *Amashaya gata Kapha* and *Pitta Dosha* thereby help in reducing the symptoms of *Amlapitta*.

Amalaki is having *Amlapradhana Lavana Varjitha pancharasa*, *Ruksha*, *Laghu Guna*, *Sara*, *Madhura Vipaka*, *Sita Virya*. Its *Vatahara* by *Amla Rasa*, *Pittahara* by its *Sita Virya* and *Madhura Vipaka*. *Kaphahara* due to its *Ruksha guna* and *Kashaya Rasa*. It helps in normalising the *Drava guna* and *Tejo guna* of *Pitta Dosha* along with pacifying *Vata* and *Kapha Dosha* thereby helping in reducing the symptoms of *Amlapitta*.

Sariva is having *Madhura*, *Tikta Rasa*, *Guru Snigdha Guna*, *Sita Virya*, *Amadoshahara*, *Tridoshahara*, *Agnimandhya* and *Aruchihara*. It acts in *Amlapitta* by pacifying the increased *Ushna Guna* of *Pachaka Pitta* thereby having its action on *Agni Sthana*. Studies showed its action through mucoprotective action selectively inhibiting prostaglandin PGF2 alpha var. indicus and it exerts mucoprotective effect comparable with standard drugs Ranitidine and Omeprazole.

Pippali is having properties like *Katu Rasa*, *Anushna Virya*, *Laghu*, *Tikshna Snigdha Guna* and *Madhura Vipaka*, *Tridoshahara*, *Rechani*, *Agnivardhana*, *Amadoshahara*. By its *Rechana* property excess accumulated *Pitta* is evacuated from *Koshta* and its action on *Agni* corrects the *Rasadhatwagni* which prevents the *Ama* formation and *Vidagdhattha* of *Anna Rasa*. It contains main Phyto constituents like Piperine. Studies conducted on Piperine showed, it inhibited the volume of gastric juice, gastric acidity, and pepsin A activity. Piperine has protective action against gastric ulceration which can be inferred as its gastric acid neutralizing affects and protection of gastric mucosa.

Sarkara which is added acts as *Pitta Samana* and balances the action of all other drugs. It also helps in maintaining the electrolyte imbalances in the body.

After the intervention, there was no reported adverse effects. None of the patients reported with severe abdominal colic, increased frequency of bowel movements, vomiting etc. There was a mild increase in burning sensation inside the mouth reported by a patient who was having *Pitta* predominance. It was subsided after administering the medicine with milk. The frequency of bowel movements reported by patients were one to two times per day. On administering the medicine after food, it was noted that there was no increased frequency of bowel movements. Time of administration of medicine was selected after food in a view of *Kapha kala* which might help in the formation of *Anna rasa* devoid of *Ama* by pacifying the *Vikrita Kapha Dosha* formed after the food intake. This facilitates the formation of normal *Pitta Dosha*.

CONCLUSION

After the study, *Trivritadi yoga* granules were found to be very effective in reducing the signs and symptoms of *Amlapitta*. Majority of the patients got improved with the symptoms of indigestion, poor appetite and helped in regular bowel movement which contributed to their better quality of life. After the study it is inferred that, the formulation *Trivritadi yoga* is found to be a step more beneficial in *Kapha Dosha* predominant *Amlapitta*. No adverse effects were reported during the entire period of study. The present clinical study was carried out on a limited number of patients. Hence, an extended study with more clinical assessment parameters and a large sample size can be considered to find the better efficacy of the formulation.

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