

A RANDOMIZED COMPARATIVE CLINICAL STUDY OF PHALATRIKADI GHANVATI AND TABLET RANITIDINE IN MANAGEMENT OF URDHVAG AMPLAPITTA

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ABSTRACT

Amlapitta is very common disease prevailing among society affecting health and daily routine of an individual. It is mainly caused due to impairment of *Jatharagni* due to various factors. There have been drastic changes in lifestyle, improper dietary patterns, changes in food culture, excessive consumption of tea, coffee, junk food, cold drinks, alcohol, increased use of NSAIDs, Aspirin etc. People find it difficult to follow rules described in Ayurved i.e. *Dincharya*, *Ritucharya*, *Ahara*. Hence, *Phalatrikadi ghanvati* was selected for study having the properties such as *Deepana*, *pachana*, increases strength of *Agni* and also helps in *Amapachana* and thus helps to break the *samprapti* of *Amlapitta*. The observations were drawn from the results obtained from the study on 70 patients. Statistical analysis was done. *Phalatrikadi ghanvati* showed 56.22% and Tablet Ranitidine showed 41.15% results in all signs and symptoms of *Urdhvag Amlapitta*. Thus, *Phalatrikadi ghanvati* showed significantly effective results as compared to Tab. Ranitidine with low frequency and intensity of relapse of symptoms after treatment.

Keywords: *Amlapitta*, *Ayurved*, *Agni*, *Phalatrikadi ghanvati*, Tablet Ranitidine

INTRODUCTION

Food is the third most essential thing for sustaining life with air and water. This shows the importance of food and it is the biggest pleasure aid for human beings in modern civilizations. Various factors influence our digestion and if not paid attention may result in various health problems.

The rules for healthy life as described in Ayurveda like *dincharaya*, *ritucharaya*, *ahara* and *Ashtau-Ahar Vidhi Visheshayatana* is difficult to follow due to changing lifestyle. Ayurveda has references of im-

portance of *Agni* and should be protected for healthy life. The impairment of *Agni* produces *Agnimandya* leading to various diseases.

Amlapitta is one of the diseases described due to impairment of *Jatharagni* and commonly seen in society. The direct reference of this disease is not found in *Brihatrayi*. The etiopathogenesis and management of *Amlapitta* on basis of *Doshas* was first described in *Kashyapa Samhita*. This disease is described along with management by *Acharyas Chakradutta*,

Madhavkar, Bhavprakash and Yogaratnakar. Acharya Charaka has mentioned Amlapitta while describing the symptoms of Ajirna but has no further description. Madhavkara described two types of Amlapitta according to gati namely Urdhvag and Adhoga.

The prevalence range of GERD was found to be 11% to 38.8% in world population. Due to recent advancements and changing lifestyle the prevalence of various diseases is increasing day by day.¹

Nidana:

The principle causative factors had been listed by Madhavkara and Kashyapa including Vriuddha ahra, Dushta ahara, Ritu vishesha i.e. Varsha, Sharad ritu (Naturally Pitta is in Vriddha state). (S., Madhav Nidanam with Madhukosha Sanskrit commentary, 2009) (H., 2008)

Samanya Lakshana:

1. Avipaka (indigestion)

2. Klama (psychologically tired without doing work etc.)
3. Utklesha (Nausea)
4. Tikta and amlodgar (Acid eructations etc.)
5. Gourava (body heaviness)
6. Hrutkantha daha (Heart burn)
7. Aruchi (Anorexia)

Prognosis:

- 1) Amla pitta of recent origin is Sadhya.
- 2) Chronic amlapitta is Yasya (i.e. maintainable)
- 3) If proper dietic care is taken, even Kasta-sadhya types of amlapitta are treatable.

Need of study:

Phalatrikadi ghan vati was selected for this clinical study mentioned in Chakradutta for management of Amlapitta. It is compared with most commonly used H₂blocker (Tablet Ranitidine) in present study.

Ingredients –

Table 1: Amalaki, Bibhitaka, Haritki, Patola, Tikta, Yashtimadhu.

Sr.no.	Drug (Sanskrit name)	Latin name	Pharmacological activities (Levekar, et al., 2007)
1.	Amalaki	Emblica officinalis Gaertn	Cholagogue, antioxidant, antacid and protective by nature
2.	Bibhitaka	Terminalia chebula Retz	Cholagogue, purgative, antiemetic
3.	Haritaki	Terminalia bellirica Roxb	Cholagogue, antiulcer and maintains gut transit time
4.	Patola	Trichosanthes cucumerina Roxb	Cholagogue, tonic, febrifuge, laxative, anti-inflammatory
5.	Yashtimadhu	Glycyrrhiza glabra Linn	Tonic, mild laxative
6.	Kutaki	Picorrhiza kurroa Linn	Reputed as antiperiodic, cholagogue

H₂ BLOCKER DRUG – TAB.RANITIDINE 150mg:

H₂ blockers are the first class of highly effective drugs for acid peptic disorder, but have been surpassed by proton pump inhibitors.

Pharmacological actions –

- a. H₂ blockade – Cimetidine and all other H₂ antagonist block histamine induced gastric secretion and bronchial relaxation.
- b. Gastric secretion – The only significant in vivo action of H₂ blocker is marked inhibition of gastric secretion. All phases of secretions are suppressed dose-dependently, but the basal nocturnal acid secretion is suppressed more completely. Secretory response to not only histamine but also other stimuli is attenuated. The volume, pepsine

content and intrinsic factor secretions are reduced, but the most marked effect on acid. However, normal vit B₁₂ absorption is not interfered, no vit B₁₂ deficiency occurs even after prolonged use.

Method of preparation of Phalatrikadi Ghan Vati:

All the above 6 drugs were taken in equal quantity in coarse powdered form and mixed thoroughly. Then the drugs were mixed with 16 times water and boiled. The resultant solution was thoroughly sieved with the help of a cloth again brewed till it becomes thick. The solution was then dried and made into form of Vati.

Aim and Objectives:

1. To compare the efficacy of the trial drug with the control group
2. To observe the relapse of symptoms if any.

MATERIALS AND METHODS:

The present clinical study was conducted at Department of *Kayachikitsa, Ayurveda Rugnalaya*, Nigdi Pradhikaran. For this clinical study total 74 patients were registered and patients from OPD and IPD were selected based on the criteria of selection. An informed and written consent was taken from all patients before starting the therapy.

Source of Data:

Various *Ayurvedic samhitas*, Journals, articles and Google scholar.

PREVIOUS WORK DONE:

- 1) 1993 – Tiwari Shanti – The role of *Pugakhanda* in management of *Amlapitta* and *Shoola*, IPGT Jamnagar.
- 2) 1995 – Vedi S.K. – Clinical study on *Amlapitta* with special reference to its management by *Avipattikar yoga*, BHU.
- 3) 2002 – Sawant P.S. – To study the efficacy of *Avipattikar Churna* in *Urdhvac Amlapitta*, M.U.H.S. Nashik.
- 4) 2004 – Sai Sudhakar P. – A clinical evaluation of *Shankha Bhasma* and *Amalaki Choorna* in *Amlapitta*, Hyderabad.
- 5) 2007 – Sahu Jaya N. – A comparative study on management of *Amlapitta* by *Patoladi Yoga* with and without *Vamana*, Ahmedabad.

STUDY DESIGN:

Type of Study – Randomized, controlled trial
 Patients diagnosed with *Amlapitta* were selected from IPD and OPD, *Kayachikitsa Dept, Ayurved Rugnalaya*. 4 patients left the schedule during the therapy period. Hence, total 70 patients completed the therapy.

INCLUSION CRITERIA:

- 1) Age group – 20 to 60 years
- 2) Gender- male and female both
- 3) Patients with signs and symptoms of *Urdhvac Amlapitta* mentioned in *Madhava Nidana*.
- 4) Patients undergone Choleectomy were included.

EXCLUSION CRITERIA:

- 1) Patients suffering from Gastric ulcer and duodenal ulcer.
- 2) Pregnant and lactating women.
- 3) Patients with renal and hepatic disorders.
- 4) Ca-stomach, oesophagus, esophageal varices, haematemesis
- 5) Major systemic diseases like DM, HTN, immunocompromised patients.
- 6) Patients with intestinal perforation, post major abdominal surgeries.

Table 2: THERAPY PLAN:

Drug	<i>Phalatrikadi ghan vati</i> (Group A)	Tab. Ranitidine (Group B)
Dose	500mg 1 tablet twice a day	150mg 1 tablet once a day
Duration	45 days	45 days
Follow up	After every 7 days	After every 7 days
Follow up after medication	At an interval of 25 days for 1 month	At an interval of 25 days for 1 month
Anupana	<i>Koshna Jala</i>	Plain drinking water

Criteria for assessment:

The effect of therapy was assessed on the basis of changes in signs and symptoms of *Urdhvac Amlapitta* in both groups.

The following signs and symptoms are assessed.

1) Chardi (vomiting):

Grade	Score	Signs & symptoms
0	0	Absent
+	1	Once in a week
++	2	2-3 times a week
+++	3	More than 3 times a week

2) Amlodgar:

Grade	Score	Signs & symptoms
0	0	Absent
+	1	Occasional
++	2	After meal
+++	3	Persistent throughout the day

3) Hrullas:

Grade	Score	Signs & symptoms
0	0	Absent
+	1	Occasional
++	2	After meal
+++	3	Persistent throughout the day

4) Shirashoola:

Grade	Score	Signs & symptoms
0	0	Absent
+	1	Occasional
++	2	After meal
+++	3	Persistent throughout the day

5) Hruda- Kantha Daha:

Grade	Score	Signs & symptoms
0	0	Absent
+	1	Occasional
++	2	After meal
+++	3	Persistent throughout the day

6) Udardaha:

Grade	Score	Signs & symptoms
0	0	Absent
+	1	Occasional
++	2	After meal
+++	3	Persistent throughout the day

7) **Aruchi:**

Grade	Score	Signs & symptoms
0	0	Absent
+	1	Twice or thrice a week
++	2	After meal
+++	3	Persistent throughout the day

Table 3: Overall assessment of criteria:

Score	Signs & symptoms
1-9	Mild
10-19	Moderate
19-28	Severe

OBSERVATIONS:

Demographic data-

Trial drug – Phalatrikadi |Ghanvati

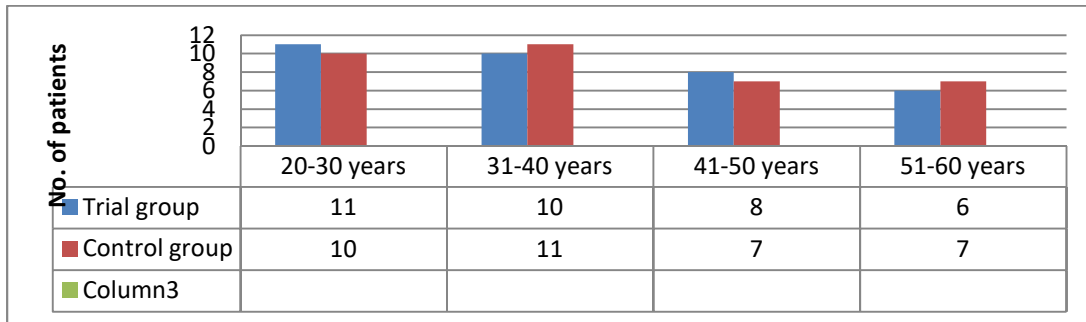
Control drug – Tablet Ranitidine

Most patients were observed in age group 20-30 years and females with more housewives.

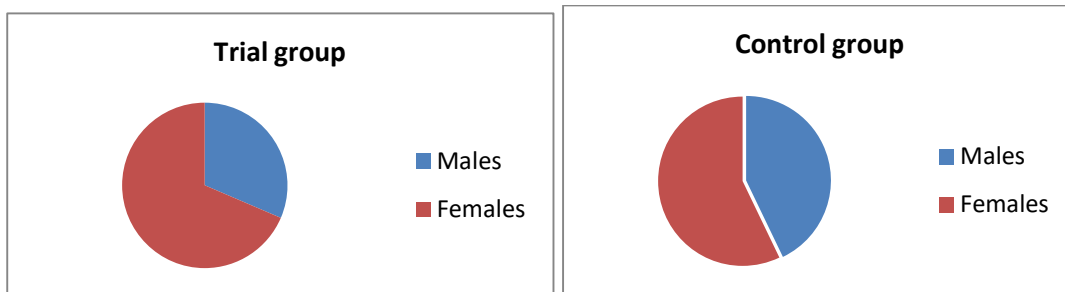
Diet-Mixed with *Katu rasa pradhana*

Predominance – *Manda Agni, Madhyama Koshtha, Pitta-Kapha prakruti, Alpanidra, Asamyak mala pravrutti*, moderate stress.

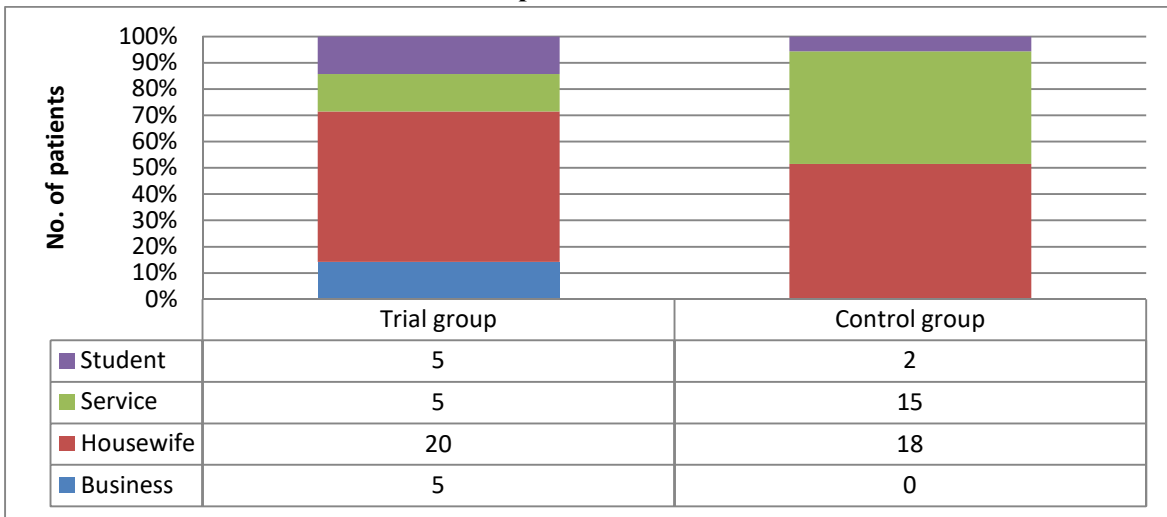
A. Age wise distribution:



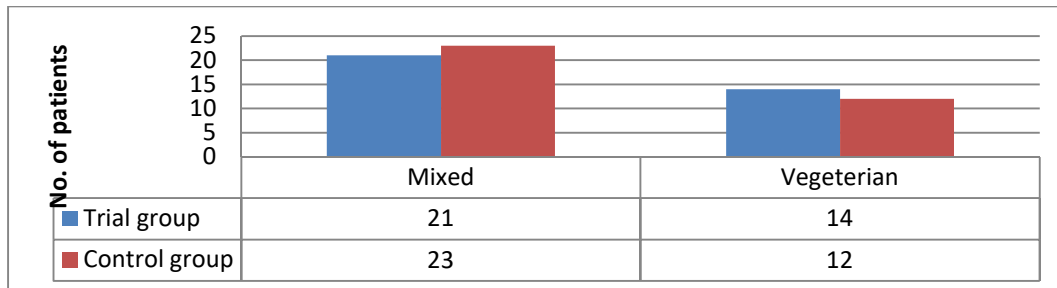
B. Gender wise distribution:



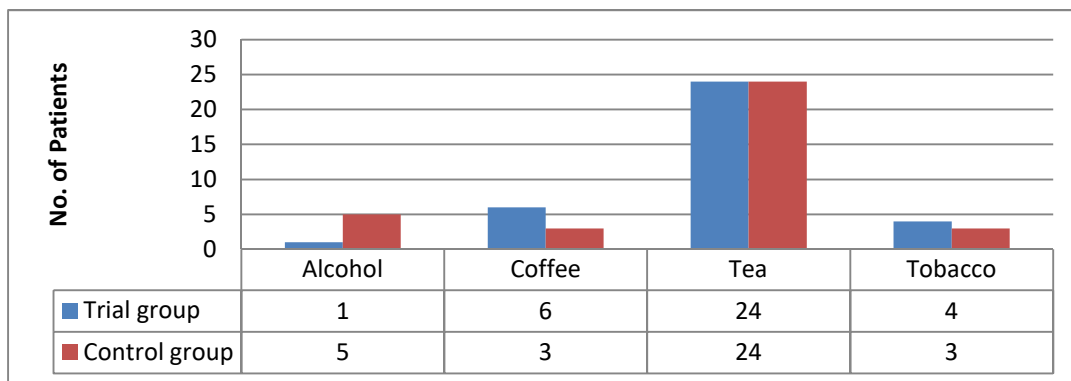
C. Occupation wise distribution:



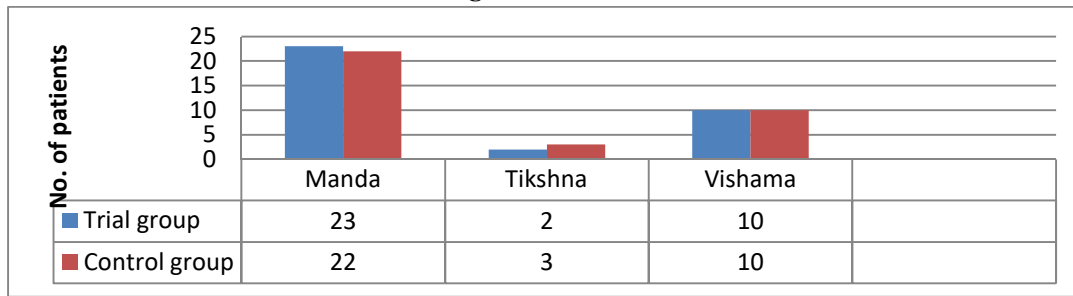
D. Diet wise distribution:



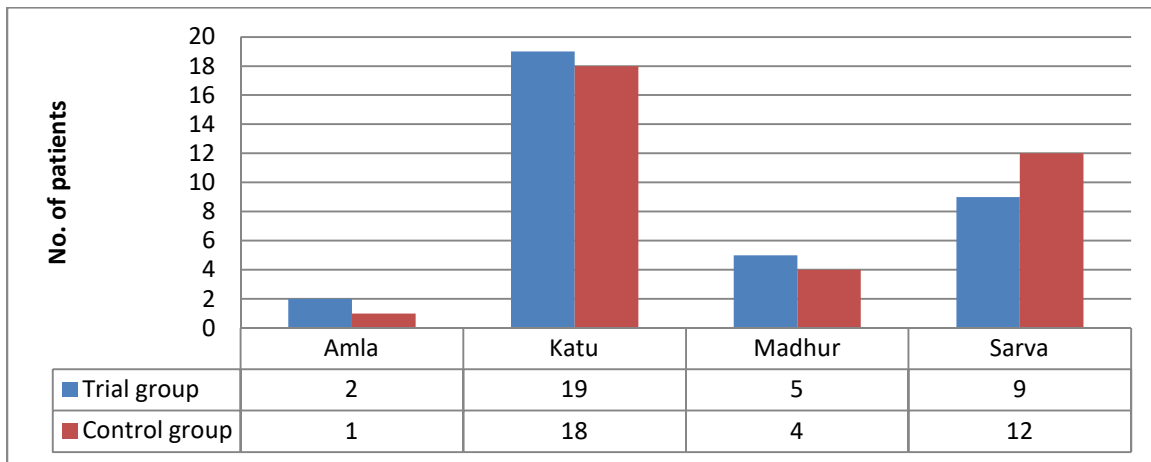
E. Addiction wise distribution:



F. Agni wise distribution:



G. Pradhan rasa wise distribution:



H. Nidra wise distribution:

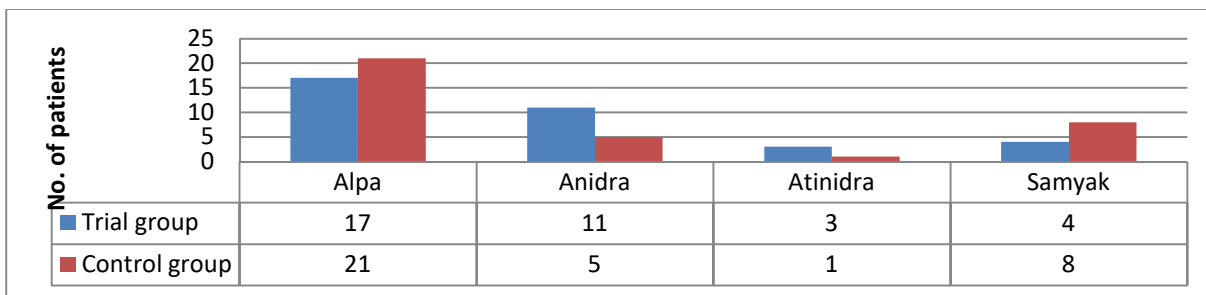


Table 4: Result:

Sign & symptoms	Group	Median		Wilcoxon Signed Rank W	p-value	% effect	Result
		BT	AT				
Chardi	A	2	1	-5.468	<0.001	66.7	S
	B	2	1	-4.811	<0.001	47.2	S
Amlodgar	A	2	1	-5.392	<0.001	69.4	S
	B	2	1	-5.289	<0.001	60.5	S
Shirashoola	A	2	0	-5.336	<0.001	68.5	S
	B	2	1	-5.166	<0.001	58.2	S
Hruda-Kantha Daha	A	2	1	-5.355	<0.001	66.3	S
	B	2	1	-5.169	<0.001	58.5	S

Udardaha	A	1	0	-5.385	<0.001	60.4	S
	B	1	0	-3.464	0.001	30.0	S
Hrullas	A	2	1	-5.161	<0.001	66.7	S
	B	2	1	-4.916	<0.001	57.4	S
Aruchi	A	1	0	-4.123	<0.001	63.0	S
	B	1	0	-3.000	<0.001	37.5	S

Comparison between Trial Group (Group A) & Control Group

Table 5: (Group B):

Sign & symptoms	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	p-value
Chardi	A	35	42.07	1472.50	382.500	0.001
	B	35	28.93	1012.50		
Amlodgar	A	35	41.66	1458.00	397.000	0.004
	B	35	29.34	1027.00		
Shirashoola	A	35	37.70	1319.50	535.500	0.228
	B	35	33.30	1165.50		
Hruda-Kantha Daha	A	35	39.56	1384.50	470.500	0.059
	B	35	31.44	1100.50		
Udardaha	A	35	44.00	1540.00	315.000	<0.001
	B	35	27.00	945.00		
Hrullas	A	35	38.43	1345.00	510.000	0.147
	B	35	32.57	1140.00		
Aruchi	A	35	39.50	1382.50	472.500	0.049
	B	35	31.50	1102.50		

DISCUSSION

Observations show that trial group is more effective than control group in symptoms like *Chardi*,

Amlodgar, *Udardaha* and *Aruchi*. No significant difference observed in symptoms like *Shirashoola*, *Hruda-Kantha Daha*, *Hrullas* in both the groups.

Table 6: The number of patients on the basis of observations:

Overall effect	Trial group	Control group
Mild improvement	7	8
Moderate improvement	10	14
Marked improvement	18	13

Trial group shows 56.22% result in all signs and symptoms of *Urdhvag Amlapitta* whereas control group shows 41.15% result.

Amlapitta is *Amashaya samutha vyadhi*. Vitiation of *Pitta dosha*, *Agnimandya* and production of *ama* were the major factor responsible for pathogenesis of the disease. In *Amlapitta Drava guna*, *Amla guna* and *Ushna guna* of *Pitta dosha* are increased. Hence, drug having properties of *Pitta shamana*, *Agni deepana* and *Amapachana* are effective in the management of *Amlapitta*.

Phalatrikadi ghanvati is an effective formulation described by Acharya *Chakradutta* in the management of *Amlapitta*. It consists of ingredients like *Patola*, *Amalaki*, *Haritaki*, *Bibhitaki*, *Kutaki* and *Yashtimadhu*. The majority of the drugs have *Tikta*, *Kashaya*, *Madhura rasa*; *Sheeta virya*, *Madhur Vipak*, *Laghu*, *Ruksha guna* and *Pitta shamana* properties. *Tikta rasa* helps in *Pachana* of *Saama Pitta*. The

shamana of vitiated *Pitta dosha* is done by *Madhura rasa*. *Kashaya rasa* helps to decrease the *Drava guna* of vitiated *Pitta dosha*. *Tikta* and *Kashaya rasa* increase the strength of *Agni* and helps in *Amapachana*. *Phalatrikadi ghanvati* helps to relieve *Chardi* and *Amlodgar* by decreasing the *Dravata guna* of vitiated *Saam Pitta dosha*. Due to its *Pitta shamaka* properties *Hruda-Kantha daha* and *Udardaha* is relieved. *Aruchi* is relieved by *Deepana* and *pachana* properties of *Phalatrikadi ghanvati*. In the present study, *Phalatrikadi ghanvati* showed significant effect on all signs and symptoms of *Urdhvac Amlapitta*. It is found effective in *Pitta shamana*, *Ama pachana* and *Agni deepana*.

CONCLUSION:

Hence, comparatively *Phalatrikadi ghanvati* is found more effective than *Tablet Ranitidine* in the management of *Urdhvac Amlapitta*. The frequency and intensity of relapse of symptoms after treatment was found very low with *Phalatrikadi ghanvati* as compared to *Tablet Ranitidine*.

Scope of Study:

The study should be carried out on large sample size after *Shodhana karma* along with diet restrictions for more better and reliable results.

REFERENCES

1. Gaddam Srinivas, Sharma Prateek, Shedding light on the epidemiology of GERD in India- a big step forward, Indian J. Gastroenterol, May-June 2011;30(3): 105-107
2. Pandit Sri Brahma Sankara Misra, edited with Vidyotini Hindi commentary, Chaukhamba Sanskrit Bhavan, Varanasi; Volume 2, Chapter 10,p.121
3. Shastri Kashinath, Edited by Pandey Gangasahay, Caraka Samhita-Vidyotini Hindi commentary, Part-2, Reprint Edition, Choukhamba Bharati Academy, Varanasi; Chapter-15/47,p.640.2004
4. Gogate V. M. – Ayurvedic Pharmacology and Therapeutic uses of medicinal plants, Bharatiya Vidya Bhavan, Mumbai, Edition-2009, p.253-256,441-443,697-699,753-757,758-760,239-241,
5. Sharma H. – Kashyapa Samhita or Vriddhajivakiya Tantra with Vidyotini Hindi commentary, Chaukhamba

- Sanskrit Sanstha Varanasi, Edition-2008;Khilasthana, Chapter 16;p.354-336
6. Shastri S.- Madhav Nidanam with Madhukosha Sanskrit commentary, Chaukhamba Prakashana, Varanasi, Edition-2009, Chapter 51;p.202
7. Walker B.R., Colledge N.R., Ralston S.H., Panman I.D.; Davidson's Principle and practice of medicine, 22nd edition, Elsevier Publication; Chapter-22,p.884.2006
8. Tiwari P V, Kashyapa Samhita of Vriddha Jivakiya Tantra, Choukhamba Vishvabharati, Varanasi, Reprint edition, Chapter16/1-30,p.630-38,2008.
9. Chakradutta by Chakrapani dutta,edited and translated by Priyavrat Sharma, Choukhamba orientalia, Chapter 52/17, Delhi,2007
10. [https://www.indianmirror.com/significanceofayurvedic herbsandtheirimportance](https://www.indianmirror.com/significanceofayurvedicherbsandtheirimportance)

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