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Clinical Study to Evaluate Efficacy of *Bhunimbadi GhanVati* and *Shatavari Ghrita* in the Management of *Amlapitta* w.s.r. to Non-ulcer Dyspepsia

Priyanka Rai*

*Deptt. of Kayachikitsa, Sri Ganganagar College of Ayurvedic Sciences and Hospital, Sri Ganganagar, Rajasthan

Abstract

Whole world is witnessing a spurt in lifestyle diseases which can be mainly attributed to rapid industrialization and urbanization. The change in lifestyle has led to an unprecedented rise in the disorders of gastrointestinal system. Disease and sufferings have become fundamental attributes of human condition. *Amlapitta* is a disease attributed to faulty dietary habits as well as to stress and strain of life. *"Hurry, Worry and Curry"* are the main attributes of *Amlapitta.* Though in modern medicine, plenty of new drugs are available to manage non-ulcer dyspepsia but all the drugs provide only symptomatic relief and none of them possess curative potentials. As these drugs are required to be consumed for a longer duration, so a lot of untoward effects are also inevitable. Hence in order to overcome these issues present study was planned to explore the efficacy of two very simple, safe and cost-effective drugs, i.e., *Bhunimbadi Ghan Vati* and *Shatavari Ghrita* in the management of *Amlapitta*. In present clinical study, *Shatavari Ghrita and Bhunimbadi Ghan Vati* were given in patients of *Amlapitta* in one group and its effects were compared with a standard H_2 blocker drug i.e., Ranitidine in other group. The effects of therapy in these two groups were then evaluated and compared.

Keywords

Amlapitta, Shatavari Ghrita, Bhunimbadi Ghan Vati

Greentree Group

INTRODUCTION

Kashyapa Samhita[1] was the first text that gave a detailed description of *Amlapitta*. *Kashyapa Samhita* has accepted the involvement of all the three doshas in *Amlapitta* whereas *Charaka Samhita* and *Madhavakara* have accepted the dominance of *Pitta dosha* in this disease. The word *"Amlapitta"* is comprised of two words – *'Amla'* and *'Pitta'*.

The term *'Amla'* refers to a particular type of taste equated with sour taste which causes excessive salivary secretions. *Pitta* is a bodily chemical substance which is mainly responsible for the maintenance of the process of digestion and transformation. *Amlapitta* is a pathological condition in which there is vitiation of *Pitta dosha* in the body. *Pitta dosha* possesses *Katu rasa,* but after it gets vitiated, the *Katu rasa* of *Pitta dosha* changes to *Amla rasa*.

Symptoms like heartburn, sour eructations, water brash, post-prandial abdominal fullness, loss of appetite, nausea, etc. are described under the heading of *Amlapitta.* The drugs selected under the study *Bhunimbadi Ghan Vati (Yogratnakar Amlapitta Chikitsa* 25)[2] and *Shatavari Ghrita (Chakradatta Chikitsa 52)*[3] contains drugs like *Bhunimba, Nimba, Triphala,*

Guduchi, Parpata, Shatavari, Patola, Vasa, Bhrihgaraja, etc. Most of the drugs have *Tikta-Madhura rasa, Sheeta virya*, *Madhura vipaka* and *laghu* properties with *Kapha-Pittahara* action. *Amlapitta* has resemblance with symptomatology of Non-ulcer Dyspepsia. Dyspepsia[4] is not one symptom but a constellation of symptoms-different in all patients. The term generally refers to pain or discomfort centered in the upper abdomen. The patients complain of early satiety, bloating, post-prandial fullness, nausea, anorexia, heart-burn, regurgitation, belching *(Sleisenger and Fordtran's.2000).* Dyspepsia is an extremely common disorder in healthy population. It accounts for upto 40% to 70% of gastrointestinal complaints in general medical practice *(Fisher.R.et.al.1998)*. One third to one half of patients with dyspepsia have non-ulcer dyspepsia *(Shah sharad et.al.2005)*. Increasing prevalence made it necessary to explore non-ulcer dyspepsia (*Amlapitta*) from literary as well as management point of view.

AIMS AND OBJECTIVES

- To evaluate the efficacy of trial drugs *Bhunimbadi Ghan Vati and Shatavari Ghrita* in the management of *Amlapitta* with special reference to Non-ulcer dyspepsia.

- To study *Amlapitta* in context of Non-ulcer dyspepsia and to review the available literature in *Ayurvedic* text and its correlation with modern literature.

METHODOLOGY

For clinical study, patients of *Amlapitta* fulfilling the diagnostic criteria were registered from the Kaya Chikitsa OPD/IPD of *Rajiv Gandhi Govt. Post Graduate Ayurvedic Hospital, Paprola, Distt. Kangra, Himachal Pradesh.*

Diagnostic criteria were mainly based on the signs and symptoms of *Amlapitta* described in *Ayurvedic* classics. They include *Hrita kantha daha, Amlodgara, Utklesha, Avipaka, Chhardi, Aruchi, Kukshi daha, Udaradhmana and Klama.*

Inclusion Criteria

- Patient willing to undergo trial and ready to give written consent.
- *Age*: 15–70 years
- *Sex*: either sex
- Patients presenting with classical features of *Amlapitta.*

Exclusion Criteria

- Patients not willing for trial.
- Patients below the age of 15 years and above 70 years.

- Patients with irritable bowel syndrome (IBS).
- History of gastric surgery.
- Uncontrolled diabetes mellitus.
- Those using aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs).
- Malignancy, cardiac problems, tuberculosis.
- Alarming symptoms like weight loss, GI bleeding and any other serious ailment.

Research Protocol

- ***IEC Approval***: Approval from Institutional Ethical Committee was obtained before the initiation of research work. (IEC/2013/353 dated 10-06-2013).

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

(1) ***Group-I (Trial group):*** 15 patients were registered in this group and they were given *Bhunimbadi Ghan Vati* (1 gm TDS) and *Shatavari Ghrita* (10 gm BD).

(2) ***Group-II (Standard group):*** 15 patients were registered in this group and they were treated with Tab. Ranitidine 150 mg BD.

Routine hematological and biochemical investigations were carried out before and after completion of trial to assess the general

condition of the patients to include them in clinical trial and to rule out any concomitant pathology. The duration of trial was 30 days. Follow up was done on 15th day and 30th day of the trial. One patient did not turn up and was considered drop out. Fourteen patients completed study in group-I and 15 patients in group-II.

% relief =

(Sum total of grade score before treatment−Sum total of grade score after treatment) x 100

Sum total of grade score before treatment

Patients were grouped under following categories on the basis of their results of the clinical trial.

• Completely relieved 100% relief from symptoms.

• Marked improvement 75–99% relief from symptoms.

• Moderate improvement 50–74% relief from symptoms.

• Slight improvement less than 50% relief from symptoms.

Statistical Evaluation and Result Analysis[5]

The entire data generated from clinical study was statistically analysed. The results were made on the basis of grades of various variables compared between pre-trial and post-trial values in terms of percentage,

Criteria of assessment

Scoring system was adopted for assessment of various subjective features and grades from zero to four were accorded to various features according to the severity. The symptoms were evaluated and response of drug was recorded in terms of percentage relief of symptoms.

based on mathematical means and its difference. Values between variables were compared with student (t) paired test for dependent samples by using the degree of freedom p value. Intergroup comparison was also done with independent (unpaired) t test. The results were expressed in terms of mean, standard deviation (SD) and standard error (SE).

• $p < 0.001$ - Highly significant

• $p < 0.01$ - Significant

• $p > 0.05$ - Non-significant

RESULTS

Grade Score method was adopted to evaluate the effect of therapy in both the groups. After completion of 4 weeks, it was

observed that statistically highly significant (p < 0.001) results were obtained in *Hrita-kantha daha, Amlodgara, Avipaka, Chhardi, Aruchi, Kukshi-daha, and Udaradhmana* in both groups. In *Utklesha and Klama,* effect of therapy was statistically significant in both group I **(Table 1)** and group II **(Table 2)** **(**p < 0.01).

Table 1 Effect of Therapy on Assessment Criteria in Group I

Parameters	N^1	Mean score		D^4	%relief	$SD^5 \pm$	$SE^6 \pm$	t^7	P^8
		BT^2	AT^3						
Hrita kantha daha	12	2.58	0.42	2.16	83.7	0.72	0.207	10.45	<0.001
Amla udgara	13	2.69	0.46	2.23	82.8	0.59	0.166	13.42	<0.001
Utklesha	10	2.10	1.0	1.10	52.3	0.74	0.233	4.71	<0.01
Aviaka	10	2.7	0.6	2.1	77.7	0.74	0.233	9.0	<0.001
Chhardi	7	2.0	0	2.0	100	0.57	0.218	9.16	<0.001
Aruchi	12	2.08	0.25	1.83	87.98	1.11	0.321	5.69	<0.001
Kukshi daha	14	2.71	0.43	2.28	84.13	0.61	0.163	13.9	<0.001
Udaradhmana	10	2.30	0.60	1.70	82.6	0.82	0.26	6.53	<0.001
Klama	12	2.16	1.66	1.50	38.4	0.95	0.275	3.63	<0.01

[[1] No. of patients having symptoms , [2] Mean score before treatment , [3] Mean score after treatment , [4] Difference in mean , [5] Standard deviation , [6] Standard error , [7] paired t test value ,[8] Degree of freedom   ]

Table 2 Effect of Therapy on Assessment Criteria in Group II

Parameters	N^1	Mean score		D^4	%relief	$SD^5 \pm$	$SE^6 \pm$	t^7	p^8
		BT^2	AT^3						
Hrita kantha daha	13	2.62	0.54	2.08	79.31	0.49	0.136	15.17	<0.001
Amla udgara	13	2.46	0.46	2.00	81.3	0.41	0.113	17.66	<0.001
Utklesha	09	2.5	1.25	1.25	50.09	0.71	0.25	5.00	<0.01
Aviaka	13	2.38	0.62	1.76	73.94	0.59	0.166	10.64	<0.001
Chhardi	09	2.00	00	2.00	100	0.82	0.258	7.74	<0.001
Aruchi	12	2.25	0.50	1.75	77.77	0.62	0.179	9.75	<0.001
Kukshi daha	13	2.53	0.38	2.15	84.88	0.55	0.153	14.0	<0.001
Udaradhmana	12	2.16	0.58	1.58	73.14	0.51	0.148	10.65	<0.001
Klama	14	2.07	1.21	0.86	41.5	0.86	0.231	3.70	<0.01

[[1] No. of patients having symptoms , [2] Mean score before treatment , [3] Mean score after treatment , [4] Difference in mean , [5] Standard deviation , [6] Standard error , [7] paired t test value ,[8] Degree of freedom]

Intergroup comparison showed statistically insignificant difference between the therapies given in trial and control group (p > 0.05).

Overall effect of therapy in both the groups

Through Grade Score system in Group-I, 7.14% patients got 100% relief. 57.14% patients were markedly improved and 35.7% were moderately improved. In group-II, 53.33% patients were markedly improved and 46.67% patients were moderately improved. **(Table 3)**

Table 3 Overall Effect of Therapy

Results	Group-I	Group-II

	No. of patients	%age	No. of patients	%age
Completely relieved (100% relief)	1	7.14	-	-
Marked improvement (75–99% relief)	8	57.14	8	53.33
Moderate improvement (50–74%)	5	35.7	7	46.67
Slight improvement (< 50%)	-	-	-	-
No improvement (0)	-	-	-	-
Symptoms became worse (−1)	-	-	-	-

Table 4 Pharmacodynamic Properties of Bhunimbadi Ghan Vati *(Yogratnakar, Amlapitta Chikitsa 25)*

Sr. No.	Drug	Rasa	Veerya	Vipaka	Guna	Karma
1	**Bhunimba**	Tikta	Sheeta	Katu	Laghu, Ruksha	Kapha-pitta shamaka
2	**Nimba**	Tikta, Kashaya	Sheeta	Katu	Laghu, Ruksha	Piita-Kapha Shamka Rakta-shodhaka
3	**Amalaki**	Pancharasa except lavana	Sheeta	Madhura	Laghu, Ruksha	Tridoshahara
4	**Bibhitaka**	Kashaya	Ushna	Madhura	Laghu, Ruksha	Tridoshahara Kapha-pitta shamaka
5	**Haritaki**	Pancharasa except lavana	Ushna	Madhura	Laghu, Ruksha	Tridoshahara
6	**Patola**	Tikta,	Ushna	Katu	Laghu, Ruksha	Piita Shamaka
7	**Vasa**	Tikta, Kashaya	Sheeta	Katu	Laghu, Ruksha	Kapha-pitta Shamaka
8	**Guduchi**	Tikta	Ushna	Madhura	Laghu, Snigdha	Tridoshashamaka
9	**Parpata**	Tikta	Sheeta	Katu	Laghu	Kapha-pittanashaka
10	**Bhringaraja**	Katu, Tikta	Ushna	Katu	Laghu, Ruksha	Kapha-vatashamaka

Table 5 Pharmacodynamic properties of Shatavari Ghrita *(Chakradatta chikitsa 52/59-60)*

Name	Rasa	Guna	Virya	Vipaka	Dosh karma
Go ghrita	Madhura	Guru, Snigdha, Mridu, Sara (purana) Manda (naveena)	Sheeta	Madhur (naveena) Katu (purana)	Vata Pitta Shamaka (naveena) Tridoshhara (purana)
Go dugdha	Madhura	Sheeta, Guru, Snigdha, Mridu Shalakshana, Picchila,	Sheeta	Madhura	Vata Pitta Shamaka
Shatavari	Madhura,Tikta	Guru, Snigdha	Sheeta	Madhura	Vata-PittaShamaka

DISCUSSION

Maximum patients 33.33% were of age group 41–50 years out of which 66.67% patients were females. Considering religion, 93% patients were *Hindu,* 93% patients were married; considering education status

of patients 60% patients were educated up to 10+2 level and 63% patients belonged to rural area.

- By profession, maximum 43 % patients were housewives, 67% patients belonged to middle class. Observations regarding dietary habits revealed that 77% patients were on mixed diet and 73% patients had additional intake of spices and chillies.

- Tea addiction was reported in 33 % patients whereas 40% patients were constipated. Appetite of 50% patients was reduced. Irregular timing of food intake was found in 37% patients. Sleep pattern of 60% patients was normal and 37% patients had sedentary lifestyle.

- Regarding *Deha Prakriti*, 43% patients were of *vata pitta prakriti*.

- In 53% of patients, the duration of illness was between 2 months and 2 years.

- *Hrita-kantha daha* was present in 83 % patients. Symptoms like *Amlodgara* (86.66%), *Utklesha* (63.33%), *Avipaka* (76.66%), *Chhardi* (53.33%), *Aruchi* (80%), *Kukshi-daha* (90%), *Udaraadhmana* (73.33%) and *Klama* (86.66%) were also recorded.

- Assessment of the patients revealed that therapies given in Group-I and Group-II were equally effective over symptoms like, *Hritakantha daha, Amlodgara Utklesha, Chhardi, Kukshi-daha. Avipaka*, *Aruchi* and *Udaradhmana* were improved to greater extent in group I whereas *Klama* was better controlled in group II.

PROBABLE MODE OF ACTION

The fundamentals regarding treatment in Ayurveda are mainly based on the *Doshik Chikitsa*. *Amlapitta*, according to *Ayurveda* is produced due to vitiation of *Pitta* mainly. Digestion process is under the control of *Pachaka Pitta, Samana Vayu* and *Kledaka Kapha*.

Bhunimbadi Ghan Vati (Yogaratnakar, Amlapitta Chikitsa 25) and *Shatavari Ghrita (Chakradatta Chikitsa 52)* have been selected as the contents are having following properties:

- Maximum ingredients of the trial drugs are having *Tikta Rasa* which is *Pitta-shamaka*.

- Maximum ingredients of the trial drugs possess *Laghu* and *Ruksha* properties.

- The drugs also possess *Deepana, Ama-Pachana, Rochana, Daha-shamaka* and *Anulomana* action.

Out of the ten ingredients of *Bhunimbadi Ghan Vati* (**Table 4**)*, Tikta*

Rasa is present in nine drugs, and *Kashaya rasa* is present in five drugs. In *Shatavari Ghrita* (**Table 5**)*,* all the three contents are having *Madhura Rasa. Tikta, Madhura* and *Kashaya Rasa* all are said to be *Pitta Shamaka* and maximum ingredients by virtue of their *rasa* alleviate the aggravated *Pitta dosha*. *Tikta rasa* has *ruksha, sheeta ,laghu* and *lekhana* properties, thus helps in the clearance of *Srotas-avarodha* caused by *Ama dosha. Tikta rasa* is also having properties like *deepana* and *pachana,* thereby aiding in *Ama pachana* . As far as *Veerya* is concerned, of all the ten contents of *Bhunimbadi Ghan Vati,* five are having *Sheeta veerya* and all the three contents of *Shatavari Ghrita* have *Sheeta veerya* which is *Pitta shamaka*

Out of ten drugs of *Bhunimbadi Ghan Vati,* four have *Madhura Vipaka* and six drugs have *Katu Vipaka*. In case of *Shatavari Ghrita,* all the three contents are having *Madhura vipaka*. The *Madhura vipaka* is said to be *Pitta Shamaka* and it has a soothing effect on the body tissues and helps in the production of fresh and healthy tissues. On the basis of this logical reasoning it may be said that in different inflammatory conditions where tissues are degenerated or have undergone ulceration, they are regenerated by the *Madhura Vipaka..*

CONCLUSION

• Trial drugs, i.e., *Bhunimbadi Ghan Vati* and *Shatavari Ghrita* were well tolerated by all the patients and no untoward effect was reported. No toxic symptom of any drug was recorded during the course of trial.

• In nutshell, it can be concluded that both the drugs, i.e. *Bhunimbadi Ghan Vati* and *Shatavari Ghrita* have *Amlapittahara* effects.

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