Clinical Study to Evaluate Efficacy of Bhunimbadi Ghan Vati 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 H2 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
INTRODUCTION

Kashyapa Samhita\textsuperscript{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)\textsuperscript{2} and Shatavari Ghrita (Chakradatta Chikitsa 52)\textsuperscript{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\textsuperscript{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 =

\[
\frac{(\text{Sum total of grade score before treatment} - \text{Sum total of grade score after treatment}) \times 100}{\text{Sum total of grade score before treatment}}
\]

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.

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

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, 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

<table>
<thead>
<tr>
<th>Parameters</th>
<th>N</th>
<th>Mean score</th>
<th>D4</th>
<th>%relief</th>
<th>SD±</th>
<th>SE±</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hrita kantha daha</td>
<td>12</td>
<td>2.58</td>
<td>0.42</td>
<td>2.16</td>
<td>83.7</td>
<td>0.72</td>
<td>0.207</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Amla udgara</td>
<td>13</td>
<td>2.69</td>
<td>0.46</td>
<td>2.23</td>
<td>82.8</td>
<td>0.59</td>
<td>0.166</td>
<td>13.42</td>
</tr>
<tr>
<td>Utklesha</td>
<td>10</td>
<td>2.10</td>
<td>1.0</td>
<td>1.10</td>
<td>52.3</td>
<td>0.74</td>
<td>0.233</td>
<td>4.71</td>
</tr>
<tr>
<td>Aviaka</td>
<td>10</td>
<td>2.7</td>
<td>0.6</td>
<td>2.1</td>
<td>77.7</td>
<td>0.74</td>
<td>0.233</td>
<td>9.0</td>
</tr>
<tr>
<td>Chhardi</td>
<td>7</td>
<td>2.0</td>
<td>0.6</td>
<td>2.0</td>
<td>100</td>
<td>0.57</td>
<td>0.218</td>
<td>19.6</td>
</tr>
<tr>
<td>Aruchi</td>
<td>12</td>
<td>2.08</td>
<td>0.25</td>
<td>1.83</td>
<td>87.98</td>
<td>1.11</td>
<td>0.321</td>
<td>15.17</td>
</tr>
<tr>
<td>Kukshi daha</td>
<td>14</td>
<td>2.71</td>
<td>0.43</td>
<td>2.28</td>
<td>84.13</td>
<td>0.61</td>
<td>0.163</td>
<td>13.9</td>
</tr>
<tr>
<td>Udaradhmana</td>
<td>10</td>
<td>2.30</td>
<td>0.60</td>
<td>1.70</td>
<td>82.6</td>
<td>0.82</td>
<td>0.26</td>
<td>6.53</td>
</tr>
<tr>
<td>Klama</td>
<td>12</td>
<td>2.16</td>
<td>1.66</td>
<td>1.50</td>
<td>38.4</td>
<td>0.95</td>
<td>0.275</td>
<td>3.63</td>
</tr>
</tbody>
</table>

[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

Table 3 Overall Effect of Therapy

<table>
<thead>
<tr>
<th>Results</th>
<th>Group-I</th>
<th>Group-II</th>
</tr>
</thead>
</table>

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

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

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Rasa</th>
<th>Guna</th>
<th>Virya</th>
<th>Vipaka</th>
<th>Dosh karma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Go ghrita</td>
<td>Madhura</td>
<td>Guru, Snigdha, Mridu, Sara (purana) Manda (naveena)</td>
<td>Sheeta</td>
<td>Madhur (naveena) Katu (purana)</td>
<td>Vata Pitta Shamaka (naveena) Tridoshahara (purana)</td>
</tr>
<tr>
<td>Go dugdha</td>
<td>Madhura</td>
<td>Sheeta, Snigdha, Mridu Shalakshana, Picchila, Mridu, Sara</td>
<td>Sheeta</td>
<td>Madhura</td>
<td>Vata Pitta Shamaka</td>
</tr>
</tbody>
</table>

**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%), Udaraadhma (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 Udaradhma 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.
REFERENCES


