



## Research Article

www.ijrap.net (ISSN:2229-3566)



### A CLINICAL STUDY TO EVALUATE THE EFFICACY OF AN *AYURVEDIC* FORMULATION IN THE MANAGEMENT OF *AMLAPITTA* WITH SPECIAL REFERENCE TO NON-ULCER DYSPEPSIA

Manu Verma<sup>1\*</sup>, B.L. Mehra<sup>2</sup>, Vikas Bharmauria<sup>3</sup>

<sup>1</sup> Assistant Professor, Department of Kayachikitsa, Abhilashi Ayurvedic College and Research Institute, Chail Chowk, Teh. Chachyot, District Mandi, Himachal Pradesh, India

<sup>2</sup> Professor and H.O.D., P.G. Department of Kayachikitsa, R.G. Government P.G. Ayurvedic College, Paprola, Teh. Baijnath, District Kangra, Himachal Pradesh, India

<sup>3</sup> Assistant Professor, Department of Shalya Tantra, Abhilashi Ayurvedic College and Research Institute, Chail Chowk, Teh. Chachyot, District Mandi, Himachal Pradesh, India

Received on: 06/07/20 Accepted on: 18/08/20

#### \*Corresponding author

E-mail: shaanvi2008@gmail.com

DOI: 10.7897/2277-4343.1105141

#### ABSTRACT

The dietary habits of present day, changing lifestyle, stress and strain related to job or domestic worries adversely impact the normal functioning of *agni* (digestive fire). Such individuals are prone to suffer from *Amlapitta* (Non-ulcer dyspepsia). The present study was conducted to explore the therapeutic potential of an *Ayurvedic* formulation containing *shankha bhasma*, *madhuyashti* and *khadira* in the management of *Amlapitta* with special reference to non-ulcer dyspepsia. The study was conducted on 30 patients selected from O.P.D. and I.P.D. of R.G.G.P.G.A.C., Paprola. Investigations were done to rule out any pathology. The subjective criteria included the symptom complex comprising *hrita kantha daha* (retro-sternal burning), *amlodgara* (sour eructations), *utklesha* (nausea), *avipaka* (indigestion) *chhardi* (vomiting), *aruchi* (loss of appetite), *kukshi daha* (epigastric burning), *udaradhamana* (flatulence) and *klama* (mental fatigue). Most of the patients showed moderate to marked improvement (~86%) in their symptoms as analyzed on visual analogue scale and grade score. The results obtained in the study revealed that the trial drug was quite effective and safe in treating *Amlapitta*.

**Keywords:** *Agni*, *Amlapitta*, Non-ulcer dyspepsia, *Shankha bhasma*, *Madhuyashti*, *Khadira*

#### INTRODUCTION

*Ayurveda* considers disturbance of “*agni*” as the root cause of all the diseases, particularly related to gastrointestinal tract (GIT) diseases.<sup>1,2</sup> *Jatharagni*, the main *agni* is the master controller of other *agnis* and is the most important factor for sustaining life of living beings.<sup>3</sup> Any disruption in the functioning of *agni* causes imbalance in the process of digestion. This leads to the vitiation of *doshas*, and *kshaya* and *vidhi* of *dhatu*s and *malas*. *Amlapitta* is also one of such diseases which occur due to *agnimandya* (reduced potency of *agni*). Due to *agnimandya*, whatever is consumed remains *vidagdha* (undigested). This *vidagdha anna* ultimately becomes *shukta* (fermented), i.e., *amlabhava* of *anna* takes place and lies stagnant in *amashaya* (stomach). When exposed to *pitta vardhaka ahara-vihara*, *pitta* gets further vitiated and gets mixed with *anna* i.e. *pitta-shukta anna sammurchhana* takes place and *Amlapitta* with its cardinal symptoms is then exhibited.<sup>4,5</sup>

The symptoms of *Amlapitta* are similar to a wide spectrum of diseases like acute gastritis, non-ulcer dyspepsia, acid peptic disorder, gastro-esophageal reflux disease etc.<sup>6-10</sup> Peptic ulcers have similar symptoms related to *Amlapitta*.<sup>11,12</sup> However, the pathophysiology and histopathology of the peptic ulcers reveal that these can't be included in *Amlapitta*, rather may be a complication of *Amlapitta*. So, the acid peptic diseases without peptic ulcers can be included in *Amlapitta*, i.e., non-ulcer acid-peptic disorders. *Amlapitta* was selected as the research topic as it is highly prevalent in the society, the manifestation of symptoms is very vast, requires prolonged dietetic control,

systemic symptoms are more predominant and if not treated in time, it may turn into an untreatable condition. Moreover, the relapses are also quite common.

#### Aims and objectives

- To study *Amlapitta* in the context of non-ulcer dyspepsia.
- To study the efficacy of an *Ayurvedic* formulation (containing *shankha bhasma*, *madhuyashti* and *khadira*) in the management of *Amlapitta* with special reference to non-ulcer dyspepsia.

#### Plan of study

To fulfill all the aims and objectives, the research work has been carried out in the following manner:

#### Conceptual Study

Detailed conceptual study was done on *Amlapitta* from available ancient and modern literature.

#### Clinical study

The present study was carried out to evaluate the clinical profile of patients suffering from *Amlapitta* vis-à-vis non-ulcer dyspepsia and to assess the effect of an *Ayurvedic* formulation in its management.

## MATERIAL AND METHODS

### Diagnostic Criteria

Diagnostic criteria were mainly based on the signs and symptoms of *Amlapitta* described in *Ayurvedic* classics. These include *hrita kantha daha, amlodgara, utklesha, avipaka, chhardi, aruchi, kukshi daha, udaradhmana* and *klama*.<sup>4,5</sup>

### Inclusion criteria

- Patients willing to undergo trial and ready to give written consent.
- Age: 18 years-70 years.
- Sex: either sex.
- Patients presenting with classical features of *Amlapitta*.

### Exclusion criteria

- Patients not willing for trial.
- Patients below the age of 18 years and above 70 years.
- Patients with IBS.
- Patients with history of gastric surgery.
- Patients with uncontrolled Diabetes mellitus.
- Patients using aspirin or other NSAIDs.
- Patients with malignancy, cardiac problems, tuberculosis.
- Patients with alarming symptoms like weight loss, GI bleeding and any other serious ailment.

### Investigations

Laboratory investigations (hematological and biochemical examination) were carried out in the beginning and at the completion of trial of every case. Endoscopy was also done in

those cases where possibility of peptic ulcer was suspected, and patient was able to afford the expenditure.

### Protocol of research

- IEC Approval
- Screening of the patients
- Enrollment

### IEC Approval

Approval from Institutional Ethical Committee was obtained before the initiation of research work (IEC/2015/1013 dated 16/06/2015).

### Screening

Patients presenting with symptomatology of *Amlapitta* were screened from Kayachikitsa OPD/IPD of R. G. Govt. P.G. Ayurvedic College and Hospital, Paprola, H.P.

### Enrollment

### Consent

Screened patients of *Amlapitta* who gave their consent and fulfilled diagnostic criteria and inclusion criteria were enrolled for the clinical study.

### Patient information sheet

Patients were detailed about the nature of disease, various aspects of clinical trial and their queries were addressed.

### Case Record Performa

Detailed case record performa was prepared which was filled up before commencement of intervention of trial drug (Table 1, Table 2 and Table 3) and after completion of the trial.

Table 1: Investigation Product

Description		
1.	Ayurvedic formulation	Shankha Bhasma + Madhuyashti + Khadira
2.	Pharmaceutical form	Capsule
3.	Dose	1 capsule TID
4.	Route of administration	Oral
5.	Frequency of administration	1 capsule TID
6.	Anupana	Water

Table 2: Composition of trial drug

S. No.	Contents	Botanical name/ Chemical name	Family	Part used	Dose
1	Shankha Bhasma	Calcium carbonate			150 mg
2	Madhuyashti	Glycyrrhiza glabra	Leguminosae	Moola (root)	200 mg
3	Khadira	Acacia catechu	Leguminosae	Khadira Saara	150 mg

Table 3: Properties of trial drug

S. No.	Contents	Effect	Reference
1	Shankha Bhasma	Tridoshaghna Rasa: Katu, Kashaya Guna: Laghu, Sheeta Virya: Sheeta <sup>13</sup>	Shankhasusheetalaha ksharastvamlapittavinashanaha. Agnimandyaharo balyo grahi grahanikaharaha. <sup>14</sup>
2	Madhuyashti	Vata-Pitta Shamaka Rasa: Madhura Guna: Guru, Snigdha Virya : Sheeta Vipaka: Madhura <sup>15</sup>	Yashti himaaguruha swadi chakshushyaa balavarnakritta. Susnigdhaa shuklaa keshyaa swaryaa pittanilarajitta. Vrana shothavishachharditrisnaglanikshayapahaa. <sup>16</sup>
3	Khadira	Kapha-Pitta Shamaka Rasa: Tikta, Kashaya Guna: Laghu, Ruksha Virya: Sheeta Vipaka: Katu <sup>17</sup>	Khadiraha sheetalo dantyaaha kandukaasaaruchipranutta. Tiktaha kashayo medoghnaha krimimehajwaravranana. Shwitrashothaamapittaasraapandukushthakaphaana hareta. <sup>18</sup>

Drug was prepared according to the standards of GMP by the Ayush Herbs Pvt. Ltd., Nagrota Bagwan, District Kangra (H.P.).

Counseling was done on every visit to relieve stress and emotional components which might trigger symptoms.

**Duration of trial:** The duration of trial was 30 days.

**Criteria of Assessment**

**Follow up:** Every 15 days till the completion of therapy.

**Visual Analogue Scale (VAS)**

The symptoms were assessed on basis of Visual Analogue scale. On the first visit 100% score of each symptom was given to the patient and in follow up after 15 days each and patients were asked to assess their symptoms on scale according to percentage.

**Dietary Instructions**

The patients were asked to avoid spicy foods, particularly red and black peppers, tea, smoking, alcohol, coffee and wine.

**Grading Score (GS)**

**Table 4: Grading Score**

Grade	Severity of Symptom	Percentage (%)
0	Absent /None	0
1	Mild	1-30
2	Moderate	31-60
3	Severe	61-90
4	Very severe	91-100

**Criteria of Overall Assessment**

The symptoms were evaluated, and response of the 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:

- 4 – Completely relieved (100 % relief from symptoms).
- 3 – Marked improvement (75 to 99 % relief from symptoms).
- 2 – Moderate improvement (50 to 74 % relief from symptoms).
- 1 – Slight improvement (less than 50 % relief from symptoms).
- 0 – No improvement
- -1 – Symptoms become worse

The entire data generated from clinical study was statistically analyzed. The results were made on the basis of grades of various variables compared between pre-trial/before-treatment (BT) and post-trial/after-treatment (AT) 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. The results were expressed in terms of mean, standard deviation (S.D.) and standard error (S.E.).

- p < 0.001- Highly Significant (HS)
- p < 0.01- Moderately Significant (MS)
- p < 0.05- Significant(S)
- p > 0.05- Non-Significant (NS)

**RESULTS AND DISCUSSION**

**Table 5: Distribution of patients**

<b>Total no. of cases registered</b>	30	100 %
<b>Total no. of cases completed trial</b>	28	93.33 %
<b>Drop out</b>	02	6.66 %

**Table 6: Demographic data**

S. No.	Demographic Profile	No. of Patients/Percentage/Maximum incidence
1.	Age	11 patients (36.66%)- 21 to 30 years, 7 patients (23.33%)-31 to 40 years
2.	Sex	20 patients (66.66%)- Female
3.	Marital status	21 patients (70%)- Married
4.	Habitat	26 patients (86.66%)- Rural
5.	Education	14 patients (46.66%)- Graduate, 9 patients (30%)- students, 6 patients each-Govt. employees, farmers
6.	Socio Economic Status	17 patients (56.66%)- Middle class
7.	Use of chili pepper and spices	18 patients (60%)
8.	Dietary Habits	18 patients (60%)- Mixed diet
9.	Addiction	12 patients (40%)- Tea, 8 patients (26.66 %)- Smoking
10.	Bowel habits	14 patients (46.66%)- Irregular
11.	Appetite	17 patients (56.66%)- Reduced
12.	Sleep	18 patients (60%)- normal sleep, 12 patients (40%)- decreased sleep
13.	Chronicity of disease	20 patients (66.66%)- 2 months to 2 years
14.	Personality	16 patients (53.33%)- assertive, 10 patients (33.33%)- anxious
15.	<i>Prakriti</i>	16 patients (53.33%)- <i>vata-pittaja</i>
16.	<i>Koshtha</i>	15 (50%)- <i>Krura koshtha</i>

## Data related to presence of Signs and Symptoms

Table 7: Effect of therapies on various symptoms in the patients of *Amlapitta*

Symptom	Scale	Mean Score			Difference of Mean	% Relief	SD	SE	t value	p value
		N	BT	AT						
<i>Hrita-Kantha daha</i>	VAS	24	100	37.91	62.08	62.08	21.055	4.298	14.446	< 0.001 HS
	GS	24	2.416	0.958	1.5	62.08	0.740	0.158	9.908	< 0.001 HS
<i>Amlodgara</i>	VAS	24	100	36.66	63.33	63.33	24.96	5.096	12.429	< 0.001 HS
	GS	24	1.458	0.416	1.042	71.46	0.550	0.112	9.278	< 0.001 HS
<i>Utklesha</i>	VAS	27	100	48.88	51.11	51.11	21.543	4.146	12.328	< 0.001 HS
	GS	27	1.66	0.518	1.153	69.21	0.543	0.106	11.177	< 0.001 HS
<i>Avipaka</i>	VAS	27	100	40.37	59.629	59.62	25.18	4.848	12.301	< 0.001 HS
	GS	27	1.703	0.629	1.0740	63.06	0.615	0.1185	9.067	< 0.001 HS
<i>Chhardi</i>	VAS	17	100	40	60	60	31.024	7.524	7.974	< 0.001 HS
	GS	17	1.176	0.352	0.824	70.06	0.528	0.128	6.424	< 0.001 HS
<i>Aruchi</i>	VAS	26	100	38.076	61.93	61.93	21.544	4.225	14.656	< 0.001 HS
	GS	26	1.461	0.5	0.961	65.77	0.527	0.103	9.291	< 0.001 HS
<i>Kukshi-daha</i>	VAS	27	100	31.85	68.148	68.148	23.376	4.499	15.148	< 0.001 HS
	GS	27	1.858	0.407	1.451	78.09	0.577	0.111	13.00	< 0.001 HS
<i>Udaradhamana</i>	VAS	26	100	48.076	51.923	51.923	28.708	5.630	9.222	< 0.001 HS
	GS	26	1.5	0.730	0.769	51.26	0.587	0.115	6.682	< 0.001 HS
<i>Klama</i>	VAS	25	100	61.2	38.8	38.8	23.635	4.737	8.191	< 0.001 HS
	GS	25	1.52	0.8	0.72	47.36	0.541	0.108	6.647	< 0.001 HS

N – Sample Size, BT – Before Treatment, AT – After Treatment, SD - Standard Deviation, SE - Standard Error, VAS - Visual Analogue Scale, GS - Grade Score, HS - Highly Significant

## Overall effect of Therapy

Table 8: Overall effect of therapy on the cardinal symptoms of *Amlapitta*

Results	Visual Analogue Scale		Grade Score	
	No. of patients	%age	No. of patients	%age
Completely relieved (100% relief)	–	–	–	–
Marked improvement (75 to 99% relief)	1	3.57%	13	46.42%
Moderate improvement (50 to 74% )	21	82.14%	11	39.28%
Slight improvement (< 50%)	6	14.28%	4	14.28%
No improvement (0)	–	–	–	–
Symptoms became worse (-1)	–	–	–	–

*Amlapitta* is an abnormal pathological condition of *pitta*. It is the disease of *annavaha srotas* caused due to *mandaagni* and *annavaha srotodushti*. *Amlapitta* is a *pitta* predominant *vyadhi* and this study showed that maximum patients had *vata-pittaja prakriti* with *pitta anubandha*. *Amlapitta* is a disease of younger and middle age group and female predominance is seen. This can be correlated as persons belonging to these age groups have predominant *pitta dosha*. Young adulthood is a stressful time, full of changes and challenges. Females are twice as likely as men to have depression and stress disorders.

*Amlapitta* is a lifestyle disorder. Indulging in faulty dietary habits, consuming ready-made food, especially oily, fried and spicy food (non-vegetarian food) causes vitiation of *pitta dosha*. Such foods require longer duration to digest and their gastric emptying is delayed. Food is retained in the stomach for longer duration which decomposes releasing harmful chemicals damaging the stomach lining. Both tea and coffee increase acid production and exacerbate symptoms in individuals. Smoking increases acid secretion and reduces sodium bicarbonate production (sodium bicarbonate causes neutralization of hydrochloric acid). Alcoholic beverages can erode the protective mucous lining of GIT leading to *amlapitta*.

In this study majority of the patients had irregular bowel habits and reduced appetite. This may be due to gastric motility disturbances and *mandaagni*, respectively, which are common in patients with dyspepsia.

Improvement in the symptoms of *Amlapitta* as per VAS system and GS system was highly encouraging. The percentage relief according to VAS Score showed marked improvement in 3.57%, moderate improvement in 82.14% and slight improvement in 14.28% of the patients. As per the Grade Score system, the calculated percentage relief showed marked improvement in 46.42%, moderate improvement in 39.28% and slight improvement in only 14.28% of the patients. Hence, majority (~86%) of the patients had moderate to marked improvement in their symptoms. Only a small percentage of patients (~14%) showed slight improvement in their symptoms. Thus, improvement in the symptoms of *Amlapitta* was statistically highly significant on the symptoms of *hrita kantha daha* (retro-sternal burning), *amlodgara* (sour eructations), *utklesha* (nausea), *avipaka* (indigestion) *chhardi* (vomiting), *aruchi* (loss of appetite), *kukshi daha* (epigastric burning), *udaradhamana* (flatulence) and *klama* (mental fatigue).

## CONCLUSION

*Amlapitta* is a GIT disorder caused due to vitiated *agni*. The predominant *dosha* involved in its pathogenesis is *pitta*. The *Ayurvedic* formulation under trial (*shankha bhasma + madhuyashti + khadira*) is quite effective and safe in treating *Amlapitta*. The positive results are attributed to the *pitta shamaka* and *sheeta virya* properties of the constituents. Thus, the combination of *shankha bhasma*, *madhuyashti* and *khadira* in the prescribed doses and duration is highly recommended drug in relieving the symptoms of a patient of non-ulcer dyspepsia.

## REFERENCES

1. Pandey K and Chaturvedi G, editors. Udara chikitsa. In: The Charaka Samhita of Agnivesha with Elaborated Vidyotini Hindi Commentary, Chikitsa Sthana. Part II. Reprint ed. Varanasi: Chaukhambha Bharati Academy; 2018. p. 3821-3.
2. Tripathi B, editor. Udara nidana. In: Ashtanga Hridaya of Srimad Vagbhatta with 'Nirmala' Hindi Commentary. Nidana Sthana. Reprint edition. New Delhi: Chaukhambha Sanskrit Pratishtan; 2013. p. 512.
3. Pandey K and Chaturvedi G, editors. *Grahani dosha chikitsa*. In: The Charaka Samhita of Agnivesha with Elaborated Vidyotini Hindi Commentary, Chikitsa Sthana. Part II. Reprint ed. Varanasi: Chaukhambha Bharati Academy; 2018. p. 459.
4. Shukla V. Chhardi evum Amlapitta. In: Kaya Chikitsa, Vol. 2. Reprint ed. Varanasi: Chaukhambha Surbharati Prakashan; 2015. p. 267-75.
5. Tripathi B, editor. Amlapitta Nidana. In: Madhava nidana of Shri Madhavakara with the Sanskrit commentary Madhukosha edited with 'Vimala' – 'Madhudhara' Hindi commentary and notes. Vol. II. Reprint ed. Varanasi: Chaukhambha Surbharati Prakashan; 2015. p. 225-30.
6. Dhawan P and Sainani R. Diseases of the Stomach and Duodenum. In: Munjal YP, editor. API Textbook of Medicine, Vol. I. 10<sup>th</sup> edition. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2015. p. 1063.
7. Abraham P. Functional Gastrointestinal Disorders. In: Munjal YP, editor. API Textbook of Medicine, Vol. I. 10<sup>th</sup> edition. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2015. p. 1103-4.
8. Tack J. Dyspepsia. In: Feldman M, Friedman LS and Brandt LJ, editors. Sleisenger and Fordtran's Gastrointestinal and Liver Disease, Vol. I, 10<sup>th</sup> ed. Philadelphia: Elsevier Saunders; 2016. p. 196-200.
9. Valle JD. Peptic Ulcer Disease and Related Disorders. In: Fauci AS, Braunwald E, Kasper DL, Hauser SL, Longo DL, Jameson JL and *et al*, editors. Harrison's Principles of Internal Medicine, Vol. I, 17<sup>th</sup> edition. New Delhi: McGraw Hill Medical; 2008. p. 1855-62.
10. Richter JE and Friedenbergh FK. Gastroesophageal Reflux Disease. In: Feldman M, Friedman LS and Brandt LJ, editors. Sleisenger and Fordtran's Gastrointestinal and Liver Disease, Vol. I, 10<sup>th</sup> ed. Philadelphia: Elsevier Saunders; 2016. p. 740-1.
11. Chan FKL and Lau JYW. Peptic Ulcer Disease. In: Feldman M, Friedman LS and Brandt LJ, editors. Sleisenger and Fordtran's Gastrointestinal and Liver Disease, Vol. I, 10<sup>th</sup> ed. Philadelphia: Elsevier Saunders; 2016. p. 886-8.
12. Dhawan P and Sainani R. Diseases of the Stomach and Duodenum. In: Munjal YP, editor. API Textbook of Medicine, Vol. I. 10<sup>th</sup> edition. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2015. p. 1064-5.
13. Premchand DY, editor. Sudha varga. In: Ayurvediya Rasa Shastra. 1<sup>st</sup> ed. Varanasi: Chaukhamba Surbharati Prakashan; 2014. p. 284-7.
14. Angadi R. Shankhaadi- Vigyaniya Taranga. In: Rasa Tarangani of Sadananda Sharma with English Commentary. 1<sup>st</sup> edition. New Delhi: Chaukhamba Surbharati Prakashan; 2015. p. 194.
15. Sharma PV. Chhedanadi varga. In: Dravya guna-Vigyana, Vol. II. Reprint ed. Varanasi: Chaukhambha Bharati Academy; 2017. p. 253-6.
16. Mishra BS and Vaisya R, editor. Haritakyadi varga. In: Bhava prakasha of Shri Bhava Mishra edited with Vidyotini Hindi commentary, Part I. 12<sup>th</sup> ed. Varanasi: Chaukhambha Sanskrit Bhawan; 2016. p. 263-4.
17. Sharma PV. Chakshushyadi Varga. In: Dravya guna-Vigyana, Vol. II. Reprint ed. Varanasi: Chaukhambha Bharati Academy; 2017. p. 159-62.
18. Mishra BS and Vaisya R, editor. Vataadi varga. In: Bhava Prakasha of Shri Bhava Mishra edited with Vidyotini Hindi commentary, Part I. 12<sup>th</sup> ed. Varanasi: Chaukhambha Sanskrit Bhawan; 2016. p. 683-4.

### Cite this article as:

Manu Verma *et al*. A clinical study to evaluate the efficacy of an *Ayurvedic* formulation in the management of *Amlapitta* with special reference to non-ulcer dyspepsia. Int. J. Res. Ayurveda Pharm. 2020;11(5):55-59 <http://dx.doi.org/10.7897/2277-4343.1105141>

Source of support: Nil, Conflict of interest: None Declared

Disclaimer: IJRAP is solely owned by Moksha Publishing House - A non-profit publishing house, dedicated to publishing quality research, while every effort has been taken to verify the accuracy of the content published in our Journal. IJRAP cannot accept any responsibility or liability for the site content and articles published. The views expressed in articles by our contributing authors are not necessarily those of IJRAP editor or editorial board members.