



## CLINICAL EFFICACY OF BALADI MANDURAM IN THE MANAGEMENT OF AMLAPITTA

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### ABSTRACT

Amlapitta is a commonly encountered disease of Annavaha Srotasa (gastrointestinal system) described in various classical Ayurvedic texts. The cardinal features of Amlapitta are Avipaka (indigestion), Hritkantha Daha (heart and throat burn) and Tikta-Amlodgara (sour and bitter belching). This disease can be correlated with gastroesophageal reflux disease based on the clinical features. Baladi Manduram is one of the unique formulations mentioned in Rasa Kamadhenu indicated for the management of Amlapitta. **Aims:-** This study is aimed to evaluate the efficacy of Baladi Manduram in the management of Amlapitta. **Materials and Methods:** A non-randomized, single clinical trial was conducted in thirty three patients having classical symptoms of Amlapitta, administered with 500 mg of Baladi Manduram twice a day after meals for 30 days. The assessment was done based on subjective parameters, i.e., Amlodgara (sour belching), Daha (heart burn), Gaurava (heaviness), Utklesha (nausea), Avipaka (indigestion) and Kshudha Alpata (loss of appetite). **Results:** Statistically highly significant relief ( $P < 0.001$ ) was noted in Amlodgara, Hritkantha Daha, Utklesha and Agnimandya and statistically highly significant relief ( $P < 0.01$ ) was seen in Gaurava and Avipaka. **Conclusion:** Baladi Manduram can be considered as an effective formulation in the management of Amlapitta.

**KEYWORDS:** Amlapitta, Baladi Manduram, gastroesophageal reflux disease.

### INTRODUCTION

Gastroesophageal reflux is a disease occurring due to improper functioning of esophageal sphincter. It is a very common disease, affecting up to 8%–20% of adult men and women in the Indian population.<sup>[1]</sup> It also occurs in children. Patients with gastroesophageal reflux disease (GERD) have the signs and symptoms such as heartburn, chest pain, gastric discomfort, abdominal distension, sour belching, food regurgitation, nausea and reduced appetite. These signs and symptoms can be seen in the disease Amlapitta mentioned in Ayurveda.

Amlapitta has been mentioned in various Ayurvedic texts since Samhita period. This disease has been described in detail in classical texts such as Kashyapa Samhita, Yoga Ratnakara, and Bhaishajya Ratnavali. Amlapitta is considered as a Pitta Pradhana Vyadhi (pre-dominant disease) and possess symptoms such as Amlodgara (sour and bitter belching), Hritkantha Daha (heart and throat burn), Gaurava (heaviness), Avipaka (indigestion), Klama (fatigue), Aruchi (tastelessness), Utklesha (nausea),<sup>[2]</sup> Antra Kujana (gurgling sounds in intestines), Hritshula (chest pain) and Vidbhedha (diarrhea).<sup>[3]</sup> Over indulgence of etiological factors such as faulty life style

causes vitiation of Vata Pitta Dosha. Pitta along with Vata or Kapha slackens the Jatharagni (diminution of digestion). During this state, consumed food becomes Vidagdha (undigested). Later on, it turns into Shukta (acidified) and it remains in the stomach for long. At this stage, Vidagdhajirna (indigestion caused due to acidified chyle) manifests which is the premonitory symptom of the disease Amlapitta. Further, vitiated Pitta gets mixed with Shukta and causes Pitta Amavisha Sammurchhana (combination of unmetabolised Rasa and undigested food with Rasa). This condition is called as Amlapitta.<sup>[4]</sup> Baladi Manduram is one of the important formulations mentioned in Rasa Kamadhenu for Amlapitta.<sup>[5]</sup> and Rasa Yoga Sagara Vol II Pakaradi Varga.<sup>[6]</sup> It contains Mandura Bhasma, Bala roots (*Sida cordifolia* Linn.), Shatavari roots (*Asparagus racemosus* Willd.), Eranda roots (*Ricinus communis* Linn.), Yava (*Hordeum vulgare* Linn.), Guda (jaggery), Jiraka (*Cuminum cyminum* Linn.), Pippali (*Piper longum* Linn.), Twak (*Cinnamomum zeylanicum* Blume), Ela (*Elleteria Cardamomum* Maton), Patra (*Cinnamomum tamala* Nees) and Nagakeshara (*Mesua ferrua* Linn.). All the ingredients present in Baladi Manduram have Kashaya (pungent), Madhura Rasa (sweet), Sheeta Virya,

Madhura Vipaka, Deepana (digestion stimulator), Krimighna (anthelmintic), Pitta–Kaphahara (pacifies Pitta and Kapha) and Shophahara (reduces oedema) properties. When combined, these drugs are expected to show their synergistic action against Amlapitta. Hence, with an intention to find the efficacy of Baladi Manduram on Amlapitta with respect to GERD, this drug has been selected.

## MATERIALS AND METHODS

A total of 33 patients having classical symptoms of Amlapitta attending the Opd of Kayachikitsa department, Jammu Institute of Ayurveda and Research were selected irrespective of sex, caste, religion etc., taking due considerations of inclusion and exclusion criteria.

### Inclusion criteria

Patients aged between 20 and 60 years having signs and symptoms of Amlapitta such as Amlodgara, Daha, Gaurava, Utklesha, Avipaka, Agnimandya were selected.<sup>[2]</sup> Diagnosis of Amlapitta was purely decided only by considering the above-mentioned signs and symptoms present in the patients.

### Exclusion criteria

Patients of age <20 years and >60 years. Patients already diagnosed with or having any history of other systemic diseases such as cardiovascular, nephropathic, neuropathic and any type of malignant disorders were excluded.

### Laboratory investigation

Routine hematological investigations such as hemoglobin percentage, total leukocyte count, differential leukocyte count and erythrocyte sedimentation rate were done.

### Posology

Baladi Manduram was given in the dose of 500 mg twice a day after meals with hot water as Anupana for a duration of 30 days.

### Diet and regimen

Pathya (wholesome diet and life style): Patients were asked to follow the meal times and to take light food, coconut water, articles having cooling properties. Vegetables like white pumpkin, bitter gourd, matured ash gourd, leafy vegetables except methi, wheat, old rice, barley, green gram, sugar candy, cucumber, fruits like gooseberry, dry grapes, black grapes, sweet lime, pomegranate, fig., adequate amount of fluids like pomogranate juice, lemon juice, amla juice, sweetlime juice, warm water, take adequate sleep and rest and to practice Yoga, Pranayama, meditation and exercise regularly.

Apathya (un-wholesome diet and life style): Avoid excessive spicy, sour, salty substances, fried and junk food items. Avoid untimely and irregular food habit,

foods containing excess amount of garlic, salt, oil, chillies etc. very often. Avoid lying down immediately after food and in supine position. Avoid smoking, alcohol, tea, coffee and stress.

### Method of preparation of Baladi Manduram

Raw materials such as Mandura and Triphala were obtained from the local market of Jammu, roots of Bala (*Sida cordifolia* Linn.), roots of Shatavari (*Asparagus racemosus* Willd), roots of Eranda (*Ricinus communis* Linn.), Yava (*Hordeum vulgare* Linn.), Jiraka (*Cuminum cyminum* Linn.), Pippali (*Piper longum* Linn.), Twak (*Cinnamomum zeylanicum* Blume), Ela (*Elleteria Cardamomum* Maton), Patra (*Cinnamomum tamala* Nees), Nagakeshara (*Mesua ferrua* Linn.), Guda (jaggery) and Kumari (*Aloe barbadensis* Mill.), Gomutra (cow urine) was collected from the Goshala Mandura was taken and subjected to Shodhana (purification) by Niravapa (quenching) in Gomutra Triphala Kashaya (decoction) for seven times. Then, the Shodhita Mandura (purified Mandura) was triturated with Kumari Swarasa (juice) and subjected to Marana (incineration) by Gaja Puta (furnace) for seven times. Guda (jaggery) was made into Paka (syrup consistency) and fine powders of herbal ingredients and Mandura Bhasma were added one by one and heated on moderate flame. After self-cooling, the mixture was dried under sunlight in a tray. Homogenous mixture of Baladi Manduram was filled in the capsules of 500 mg.

### Criteria for assessment

General observation Various demographic parameters namely, age, marital status, religion and nature of work were analyzed in the present clinical trial.

Subjective assessment Criteria of assessment was based on relief in the signs and symptoms of Amlapitta before and after the treatment.

### OBSERVATIONS

A total of 33 patients with signs and symptoms of Amlapitta were registered. In the present study, maximum number of patients, i.e., 10 (33%), were engaged with sedentary work and labor works. Maximum number of patients, i.e., 24 (80%), consumed mixed diet; 8 (26%) patients had Mandagni (low digestion state) and Tikshnagni (hyper digestion state) each; and 7 (24%) patients had Samagni (balanced digestion state) and Vishamagni (impaired digestion state) each. Fifteen (50%) patients had disturbed sleep while 15 (50%) patients had normal sleep. Maximum number of patients, i.e., 14 (47%), did not have any addiction; 6 (20%) patients were smokers; 7 (23%) patients had habit of drinking alcohol and 3 (10%) patients had habit of chewing tobacco. Fourteen (47%) patients were of Pitta–Kapha Prakriti, 9 (30%) patients were of Vata–Pitta Prakriti and 7 (27%) patients were of Vata–Kapha Prakriti. Majority of the patients, i.e., 18 (60%), had Mridu Koshtha and 19 (63%) patients suffered some kind of emotional stress in their life. Insidious onset was

found in 22 (73%) patients, 17 (57%) patients had diet as aggravating factor, 5 (17%) patients had cold climate, 4 (13%) patients had drug, 1 (3%) patient had occupation and 3 (10%) patients had posture (lying) as an aggravating factor. Ten (33%) patients had chronicity of 1 year, 8 (27%) patients had chronicity of 2 years, 7 (23%) patients had chronicity of 3 years and the remaining 5 (17%) patients had chronicity of 4 years of the disease.

## RESULTS

Effect of Baladi Manduram on Amlapitta in thirty three patients Statistically extremely significant relief ( $P < 0.001$ ) was seen in Amlodgara, Hrithkanthadaha, Utklesha and Agnimandya and statistically highly significant relief ( $P < 0.01$ ) was seen in Gaurava and Avipaka.

### Overall assessment of therapeutic effect

The therapy had shown marked improvement in 67% of patients mild improvement in 27% of patients, and complete remission was noticed in 6% of patients.

## DISCUSSION

Amlapitta is a Pitta dominant disease in association with Kapha and Vata Dosha. Excess formation of vitiated Pitta is the main pathological mechanism behind manifestation of this disease. The Pitta gets vitiated due to improper dietary and lifestyle habits. The drugs that have Tikta–Madhura Rasa (bitter–sweet taste), Madhura Vipaka (post digestive effect in sweet taste), Sheeta Virya (cooling energy of substance), Laghu (light), Ruksha Guna (dry) and pacifies to Pitta-Kapha properties are beneficial in the management of Amlapitta. Numerous herbal and herbomineral formulations are mentioned in Ayurvedic classics for the management of Amlapitta. No previous research works have been carried out in this formulation indicated for Amlapitta. Hence, the formulation Baladi Manduram has been selected for the present research work to evaluate its efficacy in the management of Amlapitta.

### Effect of Baladi Manduram on subjective parameters

Effect on Amlodgara Amlodgara is mentioned as one of the balanced Pitta symptoms.<sup>[13]</sup> Normal Pitta has Katu Rasa (pungent), but in Vidagdha state, it is transformed to sour taste. The sour and liquid properties of Pitta are also increased, resulting in impaired digestion, indigestion and leads to Amla/Tikta Udgara. The significant relief in this symptom may be due to Snigdha (unctuous), Laghu (light) and Picchila Guna (lubricous property) and Katu Vipaka (post digestive effect in pungent flavour) of Bala, Shatavari, Eranda, Pippali and Chaturjataka,<sup>[14]</sup> Ama Pachana (digestion of unmetabolised food) property of Nagakeshara, Twak and Patra.<sup>[15]</sup>

Effect on Hrithkanthadaha Hridkantha Daha mainly occurs due to Pitta Prakopa and Kapha Kshaya. Significant relief in this symptom may be due to Sheeta

Guna and Sheeta Virya of Mandura Bhasma<sup>[16]</sup> and jaggery. Vitiated Pitta might have got normalized due to pacification of Pitta, property of Bala, Shatavari, Eranda, Yava and Guda.<sup>[17]</sup>

Effect on Utklesha Utklesha mainly occurs because of excess Sama Pitta with involvement of Kapha. The significant relief found in this symptom may be due to sweet, pungent, astringent taste of Mandura Bhasma, Twak, Nagakeshara and Shatavari.<sup>[18]</sup>

Effect on Agnimandya Statistically highly significant relief was seen in Agnimandya. This improvement may be due to Stomachic, Digestant and faecal astringent properties of Mandura Bhasma, Pippali, Jiraka, Patra, Ela and Twak.<sup>[19]</sup>

Effect on Avipaka Mandagni leads to Ajirna (Vidagdhajirna) which in turn leads to Amlapitta. The significant relief found in this symptom may be due to digestive property of Pippali, Jiraka, Nagakeshara, Twak and Ela<sup>[20]</sup> and Ama Pachana (digestion of unmetabolised food) property of Twak, Nagakeshara, Jiraka and Ela.

Effect on Gaurava This symptom is due to Kapha Prakopa. The significant relief found in this symptom may be due to pacification of Kapha, Lekhana (scraping) and Laghu (light) property of Mandura Bhasma, Pippali, Jiraka and Eranda.<sup>[21]</sup>

### Probable mode of action of Baladi Manduram

Evaluation of five fundamental parameters of drug (Rasa Panchaka) for Baladi Manduram suggests that it is sweet, astringent in taste, light, irritant in nature, cool property, cooling energy of substance. It has Madhura Vipaka (sweet post digestive effect), vitiated Pitta-Kapha, Stomachic and digestive process of un-metabolised food, analgesic and anti-inflammatory properties. Mandura Bhasma has astringent taste, dry, light, cool potential, post digestive effect in pungent flavour, Stomachic and pacifies Pitta-Kapha property. By virtue of its taste and properties, it pacifies aggravated pitta and thereby improves the digestion and metabolism. Intake of iron oxide helps in reducing the excess digestive acid secretion from the gastric mucosa.<sup>[22]</sup> Bala has Balya property (increase strength), pacifies to Vata, scraping effect and pacifies Tridosha. It has anti-inflammatory, analgesic and wound-healing properties.<sup>[23]</sup> Shatavari roots has Agni Vardhaka (digestive stimulant), Vayah-Sthapana (anti ageing), rejuvenator effect and increases strength. Research studies on *Asparagus racemosus* have shown that it has antidyspepsia, antiulcerogenic and antioxidant properties.<sup>[24]</sup> Eranda roots has Ama Pachana (digestion of unmetabolized food) and aphrodisiac properties and antiulcer, anti-inflammatory, antihistaminic and antioxidant activities.<sup>[25]</sup> Yava has antioxidant and anti-inflammatory activities.<sup>[26]</sup> Pippali and Jeeraka have Deepana, Vata–Kaphahara, aphrodisiac and rejuvenator properties and anti-inflammatory, antioxidant, analgesic and antiulcer activities.<sup>[27]</sup>

Chaturjataka (Twak, Ela, Patra and Nagakeshara) pacifies Vata-Kapha, possess Stomachic, Digestant, antihistaminic and anti-hemorrhoidal, gastroprotective, antispasmodic, anti-inflammatory and antioxidant properties.<sup>[28]</sup> Due to the presence of above-mentioned properties, Baladi Manduram helps in reducing the aggravated Pitta Dosha, stabilizes the state of Agni, helps in Ama Pachana (digestion of unmetabolised food), pacifies Vidagdhajirna and thereby improves digestion, absorption and assimilation, thus relieving the symptoms of Amlapitta.

## CONCLUSION

Baladi Manduram has provided significant results on the parameters of Amlapitta. Based on the present clinical study, it can be concluded that Baladi Manduram is an efficacious formulation for the management of Amlapitta. No adverse effects were reported during the entire study period. The present clinical trial was carried out on a limited number of patients. Hence, an extended study with more clinical parameters and on a large number of patients can be considered to find the effect treatment prevention of recurrence.

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