Clinical efficacy of *Baladi Manduram* in the management of *Amlapitta*

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Abstract

Background: *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-armed, open-labeled clinical trial was conducted in thirty 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). The results were statistically analyzed using the paired *t*-test. **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.^[1] 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),^[2] *Antra Kujana* (gurgling sounds in intestines), *Hritshula* (chest pain) and *Vidbheda* (diarrhea).^[3]

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Quick Response Code:

Website: www.ayujournal.org

DOI: 10.4103/ayu.AYU_201_17

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* factor responsible for digestion, i.e., *Jatharagnimandya* (dimunition 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 premonitary 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*.^[4]

Baladi Manduram is one of the important formulations mentioned in Rasa Kamadhenu for Amlapitta.^[5] and Rasa Yoga

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How to cite this article: Kumar HK, Sridurga CH, Rao DB. Clinical efficacy of *Baladi Manduram* in the management of *Amlapitta*. Ayu 2017;38:133-8.

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Sagara Vol II Pakaradi Varga.^[6] 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 (pocifies 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 *Roga Nidana* and *Rasa Shastra & Bhaishajya Kalpana* department from Institute hospital, were selected irrespective of sex, caste, religion etc., taking due considerations of inclusion and exclusion criteria. The study was started after approval from the Institutional Ethics Committee (IEC/SVAYC/RS/15/49) dated 26-3-2015. Informed written consent was taken from each patient before starting the treatment.

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.^[2] 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.

Statistical analysis

Statistical test for assessment of the data was performed using the paired *t*-test using GraphPad Prism software, USA.

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 Chennai, Tamil Nadu, India. 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 barbadenisis* Mill.) were obtained from the TTD, Sri Srinivasa Ayurvedic Pharmacy, Tirupati, Andhra Pradesh, India. *Gomutra* (cow urine) was collected from the TTD Goshala, Tirupati, Andhra Pradesh, India.

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. For this purpose, cardinal signs and symptoms were given scores.

Symptom score	
1. Amlodgara	Grade
No belching	0
Feeling of belching with no sound	1
Feeling of belching with mild sound	2
Feeling of belching with severe sound	3
2. Daha	Grade
No burning sensation (no retrosternal discomfort)	0
Sensation of warmth on throat occasionally	1
Burning sensation on throat and chest after a mild	2
oily/spicy food	
Feeling of burning sensation always	3
irrespective of the diet	
3. Gaurava	Grade
Normal	0
Feeling of heaviness in morning	1
Feeling of heaviness in morning and evening after foo	d 2
Feeling of heaviness always	3
4. Utklesha	Grade
No nausea	0
Mild nausea	1
Severe Nausea	2
Severe nausea with vomiting	3
5. Avipaka	Grade
No indigestion	0
Unable to digest mild fatty food	1
Unable to digest 3-course meal	
(breakfast, lunch and dinner)	2
Unable to digest any kind of food	3
6. Agnimandya	Grade
Normal	0
Only takes lunch and dinner	1
Loss of interest in lunch or dinner	2
No desire to take food	3
Criteria for overall effect of therany	

Criteria for overall effect of therapy

The total effect of the therapy was assessed considering the following criteria - Complete remission: 76%-100%, Markedly improved: 51%-75%, Mild improvement: 26%-50%, No improvement: <25%.

Statistical evaluation of results

The obtained information was analyzed statistically in terms of mean score (x), standard deviation, standard error. Paired t-test was conducted at the level of 0.05, 0.01 and 0.001 of *P* levels. The results were interpreted as follows - Insignificant: P > 0.05, Significant: P < 0.05, Highly significant: P < 0.01, Extremely significant: P < 0.001

Observations

A total of 33 patients with signs and symptoms of Amlapitta were registered. Out of them, 30 patients completed the course of treatment. Two patients dropped out due to unknown reasons, whereas one patient dropped due to transfer of job

AYU | Volume 38 | Issue 3-4 | July-December 2017

to the other state. In the present study, maximum number of patients, i.e., 10 (33%), were between 20 and 29 years of age group, 8 (27%) patients were between 30 and 39 years of age group 6 (20%) patients were between 40 and 49 years of age group and 50 and 60 years of age group each. Eighteen (60%) patients were male and the rest of the patients, i.e., 12 (40%), were female; maximum number of patients, i.e., 28 (94%), were Hindu and 23 (77%) patients were married. Seventeen (57%) patients were from urban area, while 13 (43%) patients were from rural area. Majority of patients, i.e., 17 (57%), were educated and 19 (63%) patients belonged to middle class. Total 12 (40%) patients were doing moderate work whereas 9 (30%) patients 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 sufferd 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 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 [Table 1].

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 [Table 2].

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

Parameters	п	Mean		Mean difference	Relief (%)	SD	SE	t	Р
		BT (O day)	AT (30 day)						
Amlodgara	30	1.96	0.63	1.33	68	0.71	0.13	10.26	< 0.001
Hrithkantadaha	30	1.9	0.76	1.14	60	0.6	0.11	9.87	< 0.001
Gaurava	25	1.64	0.88	0.76	46.30	0.4	0.08	8.71	< 0.01
Utklesha	20	1.7	0.75	0.95	55.80	0.67	0.15	6.19	< 0.001
Avipaka	23	1.65	0.82	0.83	50	0.76	0.16	5.09	< 0.01
Agni Mandya	25	2.08	0.96	1.12	53.80	0.8	0.16	6.72	< 0.001

n: Number of patients suffering from symptom, BT: Arithmetic mean of scoring before treatment, AT: Arithmetic mean of scoring after treatment, SD: Standard deviation, SE: Standard error, P: Significance of treatment on specific symptom

Table 2: Overall assessment of clinical trial				
Result	Number of patients (%)			
Complete remission	2 (6)			
Marked improvement	20 (67)			
Improvement	8 (27)			
No improvement	0 (0)			

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*.

In the present study, maximum number (60%) of patients belonged to middle age, which is Pitta-predominant period of life. This may be due to the adoption of busy lifestyle, habitualization to unhealthy food habits and irregular daily regimen, stress and addictions in this age group. Most (57%) of the patients belonged to urban habitat. Urbanization leads to increased pollution; fast and modernized lifestyle; irregular food habits; stressful condition; and usage of fast foods, food additives, adulterants and preservatives. Maximum (57%) numbers of patients were educated. It shows that in this fast and competitive era, stress is the predominant causative factor in developing Amlapitta among educated people. Most of the patients in this study were nonvegetarian; Madhava Acharya has mentioned excess consumption of nonvegetarian food and Vidahi Annapana (foods which cause burning sensation inside) as cause of Amlapitta.^[7] Maximum (63%) numbers of patients belonged to middle class; the probable explanation for this high incidence may be irregular dietary habits and occupational stress in them. It is evident that the middle class are more prone to stress and strain in their routine life either socially or financially. In the present study, 26% of patients suffered from Mandagni (lowered digestive state) and Tikshnaagni (hyper digestive state) and 24% of patients suffered from Vishamagni (impaired digestive state) and Samagni (balanced digestive state). Classics has mentioned

that Mandagni is the main reason for the development of all diseases.^[8] Mandagni is the root cause of Ama (toxic residue which is produced after indigestion) formation and it is Ama which is responsible for the development of Vidagdhajirna (early changes of Amlapitta). Tikshnaagni causes excess secretion of gastric juice, which irritates gastric mucosa. Nearly 50% of patients had disturbed sleep while 50% had normal sleep. This type of sleeping habit may be due to discomfort of the disease or extra hours of sleep during daytime which leads to Ajirna. Diwaswapna (day sleep) vitiates Tridosha as per Sushruta and especially Pitta and Kapha Dosha as per Charaka.^[9] Disturbed sleep increases psychological stress which leads to impairment of Agni. This is one of the cause of Amlapitta.[7] Habit of drinking alcohol was noticed in 23% of patients while 20% were smoker and 10% had a habit of chewing tobacco. Intake of alcohol vitiates all qualities of Pitta. Excessive intake of tobacco, gutkha and pan-masala may impair Agni and lead to manifestation of Amlapitta. These factors cause irritation of gastric mucosa and vitiate Dosha mainly Pachaka Pitta and Kledaka Kapha.[4] Majority (47%) of patients belonged to Pitta-Kapha Prakriti, as Doshik predominance of disease is Pitta Kapha, so more number of people were of this *Prakriti* when compared to others. These patients are prone to Amlapitta due to intake of Tikshna (spicy), Ushna (hot), Lavana (salty), Khara (rough), excessive cold and heavy foods. Nearly 60% of patients had Mrudu Koshtha, excess Pitta in any form will have an effect on Koshtha and in this case, the Sara (mobile), Drava (liquid) Guna of Pitta, leads to Mrudu Koshtha.

In the present study, 63% patients had emotional stress. Stress is something that stimulates our body to respond in an abnormal way. The mental stress and strain leads to irregular fluctuations in the production of gastric secretions ultimately causing damage to the gastric mucosa.^[10] Vagal stimulation along with sympathetic irritation of gastric mucosa can be attributing factor for anxiety and emotional stress.^[11] Data showed that aggravating factor in 17 (57%) patients was due to diet, 5 (17%) patients due to cold climate, 4 (13%) patients due to drug intake, while 3 (10%) patients by improper posture and 1 (3%) patient had occupation as aggravating factor. Intake of spicy food, *Pitta Kaphavardhaka Ahara* (food which aggravated *Pitta* and *Kapha*) *Vitiates Pitta*, which causes *Vidagdhaajirna*. This in turn leads to *Amlapitta*.

Intake of nonsteroidal anti-inflammatory drug stimulates H₂ receptors in stomach which leads to excess gastric secretions. According to *Acharya Sushruta*, left lateral sleeping posture is considered as ideal posture because it helps in proper digestion and absorption of *Ahara*.^[12] Other postures such as supine, right lateral and prone position may cause improper gastric secretions, which leads to impaired digestion. Awaking late night and untimely food intake in software engineers, watchman etc., due to their occupation leads to *Vata Prakopa* (vitiates aggravation of *Vata*) and *Kapha Kshaya* (decreased *Kapha*), which ultimately leads to *Amlapitta*.

Effect of Baladi Manduram on subjective parameters *Effect on Amlodgara*

Amlodgara is mentioned as one of the balanced *Pitta* symptoms.^[13] 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*,^[14] Ama Pachana (digestion of unmetabolised food) property of *Nagakeshara*, *Twak* and *Patra*.^[15]

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*^[16] and jaggery. Vitiated *Pitta* might have got normalized due to pacification of *Pitta*, property of *Bala*, *Shatavari*, *Eranda*, *Yava* and *Guda*.^[17]

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*.^[18]

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*.^[19]

Efeect 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*^[20] 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*.^[21]

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, rritant 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 antiinflammatory 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.[22] Bala has Balya property (increase strength), pacifies to Vata, scraping effect and pacifies Tridosha. It has anti-inflammatory, analgesic and wound-healing properties.^[23] 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.^[24] Eranda roots has Ama Pachana (digestion of unmetabolized food) and aphrodisiac properties and antiulcer, anti-inflammatory, antihistaminic and antioxidant activities.[25] Yava has antioxidant and anti-inflammatory activities.^[26] Pippali and Jeeraka have Deepana, Vata-Kaphahara, aphrodisiac and rejuvenator properties and anti-inflammatory, antioxidant, analgesic and antiulcer activities.^[27] Chaturjataka (Twak, Ela, Patra and Nagakeshara) pacifies Vata-Kapha, possess Stomachic, Digestant, antihistaminic and anti-hemorrhoidal, gastroprotective, antispasmodic, anti-inflammatory and antioxidant properties.[28]

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.

Financial support and sponsorship Nil.

Conflicts of interest

There are no conflicts of interest.

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