ORIGINAL ARTICLE

Clinical Study to Evaluate the Efficacy of *Khanda Pippali Avaleha* in the Management of *Amlapitta*

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Abstract

Aim: To evaluate the efficacy of *Khanda Pippali Avaleha* in the management of *Amlapitta* 2 and to compare the efficacy of *Khanda Pippali Avaleha* with a standard drug. **Materials and Methods:** A total of 30 clinically diagnosed patients were selected from OPD/IPD of *Panchakarma*, Department of Rishikul Campus, Haridwar, and randomly categorized into two equal group. In Group A, *Khanda Pippali Avaleha* was administered orally in a dose of 10 g. Period of the study was for 60 days along with follow-up after 1 month. In control group, omeprazole was given in the dose 20 mg once a day for 60 days empty stomach. The assessment was done on the basis of classical symptomology of *Amlapitta.* **Results and Discussion:** Obtained results were analyzed statistically, and significance of results was evaluated (GraphPad InStat 3.10). Interventions were found to be significantly effective in reducing *Daha, Amlodgara, Shula, Chhardi,* and *Avipaka* and associated symptoms with $P < 0.001$, more percentage relief was found in *Daha, Amlodgara,* and *Shula* in patients treated with the standard drug. After 1 month of treatment, more sustained response was observed in patients treated with *Khanda Pippali Avaleha.* In Group A, only 7.69% show relapse to moderate improvement after having marked improvement. In Group B, 16.66% show relapse from marked to mild improvement. **Conclusion:** A small attempt has been made to prove *Khanda Pippali Avaleha* is quite promising and efficacious treatment; its efficacy can be better interpreted by conducting a clinical trial on large sample.

Key words: Amlapitta, Khanda Pippali Avaleha, standard drug

INTRODUCTION

In the 21st century, the era of competition life it is full with stress having more speed and accuracy are the prime demands. The needs of the human being are infinite, but the availability is less to fulfill the growing needs which have no end. Nowadays, the people are attracted toward the junk food; they are changing their diet pattern, lifestyle, and behavioral pattern working with stress and strain. Hence, the people are becoming more stressful with worry, tension, and anxiety causing, so many psychological disorders which hamper the digestion and are causing hyperacidity, gastritis, dyspepsia, peptic ulcer disorders, and anorexia. All these pathological disorders covered under the broad umbrella of "*Amlapitta*" in Ayurveda.

It is very common disease encountering in present population with more or less severity. It is the one that which bears the direct impact of the dietic errors that a person indulges. 80% of the top 10 life-threatening diseases of the world are due to faults in dietary habits.[1] Gastrointestinal disturbances are increasing and India is no exception to this. Among them, nonulcer dyspepsia, a gastrointestinal tract disorder, acquires majority of the share.[2]

Amlapitta is a burning problem of today's society. This has given rise to many other serious diseases. *Amlapitta* is the most important difficult disorder due to faulty lifestyle.[3] It is characterized by acid regurgitation, nausea, heartburn indicating the *Vikruti* of *Pachakapitta* along with *Kledaka Kapha* and *Samana Vayu*.[4]

Although there are many antacids, proton pump inhibitor (PPI) is popular and available in pharmaceutical market. In spite of this remedies from medicinal plants are used to treat this disease successfully. Plant drugs and herbal

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formulations are frequently considered to be less toxic and free from side effects than synthetic one. The US Food and the Drug Administration warned that there is increased the risk of fractures with the use of PPIs including esomeprazole, omeprazole, and pantoprazole.[5]

Looking into the above-mentioned facts, this study has been taken and there is a need for treatment which can prevent the complication of the disease, safer, cost-effective, and easily available as well as reduce the recurrence effectively. This has encouraged assessing the effect of ayurvedic palliative drug, i.e., *Khanda Pippali Avaleha. Khanda Pippali Avaleha* contains drugs such as *Pippali, Shatavari, Nagarmotha, Daalchini, Elachi, Haritaki, Godugdha,* and *Goghrita*. Most of the drugs are having *Tikta, Madhura, Kashaya*, and *Katu Rasa*, *Laghu*, and *Ushna Gunas* which act against the excessive *Drava* and *Tikshna Gunas* of *Pitta* and also having *Agnideepaka, Pittashamak*, and *Pittarechaka* properties. On the other hand, they all have a specific role in the management of *Mandagni.*

MATERIALS AND METHODS

Khanda Pippali Avaleha has been selected for the treatment of *Amlapitta* which is a classical reference mentioned in the *Yogratnakar Uttarardh Amlapitta Nidanam* [Table 1].[6]

Aims and objectives

The aim and objective of the study are:

1. To evaluate the efficacy of *Khanda Pippali Avaleha* in the management of *Amlapitta*
2. Compare the efficacy of *Khanda Pippali Avaleha* with standard drug.

Patients were selected on the basis of the presence of classical symptoms of *Amlapitta* from the OPD/IPD Department of *Panchakarma*, Rishikul Campus, Haridwar. The patients were randomly categorized into two equal groups irrespective of their gender, age, income status, etc. Routine hematological and stool examination had been carried out to rule out any other pathology and to exclude the organic disorders. Special research pro forma had been prepared and after detail history taking and examination, selected 30 patients were randomly categorized into two groups on the basis of inclusion and exclusion criteria.

Criteria for selection of patients

Inclusion criteria

1. Classical symptoms of *Amlapitta* as described in ayurvedic texts, viz., *Hrid Kantha Daah* (burning sensation in epigastric region), *Aruchi* (loss of appetite), *Utklesha* (Nausea), *Tikta Amla Udgaar* (acid

Table 1: Ingredients of *Khanda Pippali Avaleha* with the details of botanical names, parts used

Name	Rasa	Guna	Virya	Vipaka	Doshaghnata
Kapura (*Cinnamom camphora*)	Tikta	Laghu	Sheeta	Katu	Tridoshahar
Jaatiphala (*Myristica fragrans*)	Tikta	Laghu	Usna	Katu	Kapha-Vatahar
Jeeraka (*Cuminum cyminum*)	Katu	Laghu	Usna	Katu	Kapha-Vatahar
Daalchini (*Cinnamamom zeylnica*)	Tikta, Madhur	Laghu, Ruksha	Usna	Katu	Pittashamak
Naagkesar (*Messuae ferrae*)	Kasaya, Tikta	Laghu, Ruksha	Usna	Katu	Kapha-Pittahar
Elaichi (*Elletaria cardamamum*)	Katu, Madhur	Laghu, Ruksha	Sheeta	Madhur	Tridoshahar
Tejpatra (*Cinnamomum cassia*)	Madhur, tikta	Laghu, Ruksha	Usna	Katu	Vata-Pittahara
Dhyanak (*Corriandarum sativum*)	Kasaya, Tikta, Madhur	Laghu, Snigdha	Usna	Madhur	Tridoshahar
Nagarmotha (*Cyperus rotundus*)	Kasaya, Tikta	Laghu, Ruksha	Sheeta	Katu	Kapha-Pittahara
Pippali (*Pipper longum*)	Katu	Laghu, Snigdha	Usna	Madhur	Vata-Slesmahara
Banslochan (*Bambusa arundinaceae*)	Kasaya, Madhur	Laghu, Ruksha	Sheeta	Madhur	Vata-Pittahar
Satavari (*Asparagus racemosus*)	Madhur, Tikta	Guru, Snigdha	Sheeta	Madhur	Vata-Pittahar
Haritaki (*Terminalia chebula*)	Kasaya, Pradhana	Laghu, Ruksha	Usna	Madhur	Tridoshahara
Aamlaki (*Emblica officinalis*)	Madhura, Amla, Pradhan	Guru, Rusha, Sheeta	Sheeta	Madhur	Pittashamak
Krisnajeera (*Carumcarvi* Linn.)	Katu	Ruksha	Usna	Katu	Kaphahara
Maricha (*Piper nigrum*)	Katu	Laghu	Usna	Katu	Kapha-Vatahara
Sarkara	Madhur	Snigdha, Guru	Sheeta	Madhur	Vata-Pittahara
Godugdha	Madhur	Laghu	Sheeta	Madhur	Tridosahara
Goghrita	Madhur	Snigdha, Guru	Sheeta	Madhur	Tridosahara
Madhu	Madhur	Laghu	Sheeta		Tridosahara

regurgitation), *Udar Adhmana* (flatulence), *Avipaka* (indigestion)
2. Age 20-60 years
3. Gastroesophageal reflux disease (hyperacidity) without any metabolic complications.

Exclusion criteria

1. Age group <20 years and more than 56 years
2. Known case of gastric and duodenal ulcer
3. Known case of gastric cancer.

Laboratory investigations

1. Routine hematological, urine examination, stool test carried out to rule out any other pathology
2. Barium meal test (if needed)
3. Gastric juice analysis (if needed)
4. Endoscopy (if needed).

Withdrawal criteria

1. Personal matters
2. Intercurrent illness
3. Other difficulties
4. Aggravation of symptoms
5. He/she develops any serious adverse effect (necessitating hospitalization).

Randomization and blinding

Patients were randomized in a 1:1 ratio. This is an open study.

The study protocol was reviewed and approved by an Institutional Review Board at the institution level. From patients, written informed consent was taken before entering into the study. The importance of them for adherence to the treatment, *Pathya-Apathya* associated with the disease, schedule for follow-up, dates for visits to hospital was issued.

Interventions

- Drug: *Khanda Pippali Avaleha*
- Dose: 10 g
- *Anupana: Draksha Hima*
- Time of administration: In morning (empty stomach)
- Duration of therapy: 60 days
- Patients were guided regarding *Pathya/Apathya* regimen

METHODOLOGY OF ADMINISTRATION OF STANDARD DRUG

Omeprazole was administered in Group B in the dose 20 mg once a day for 60 days empty stomach.

Follow-up

After the completion of the therapy, the patient was advised to visit OPD at an interval of 15 days for 1 month.

Criteria for examination and assessment

Parameters were employed for assessment of the impact of the treatment produced in respective groups. Sign and symptoms of *Amlapitta* were looked into for assessment.

- Burning sensation in epigastric region
- Acid regurgitation
- Indigestion
- Loss of appetite
- Nausea
- Constipation
- Heaviness.

OBSERVATION

Total 30 patients were registered. Out of 30 patients, 26 patients had completed the treatment in three groups and 4 patients discontinued the treatment [Table 2].

A maximum number of patients were females, i.e., 53.33% and 50% of patients were males [Table 3].

Out of 30 patients, 53.33% were of *Mand Agni* (diminished metabolic state), 46.66% were *Visahma Agni* (irregular metabolic state) [Table 4].

Table 2: Total number of registered patients

Type	Number of patients		Total (%)
	Group A	Group B	
Complete	14	12	26 (86.66)
Lama	1	3	4 (13.33)
Total	15	15	30 (100)

Table 3: Sex-wise distribution of patients

Sex	Number of patients		Total (%)
	Group A	Group B	
Male	8	6	15 (50)
Female	7	9	16 (53.33)

Table 4: *Agni* wise (metabolic state) distribution

Agni	Number of patients		Total (%)
	Group A	Group B	
Sama	0	0	0
Manda	7	9	16 (53.33)
Vishama	8	6	14 (46.66)
Teekshna	0	0	0

About 43.33% patients reported *Soka,* 33.33% patients reported *Chinta,* and 6.66% patients reported *Krodha* in their mental status [Table 5].

About 33.33% patients have stress risk factor, 23.33% have consumption of NSAIDs, and 10% have smoking risk factor and previous ulcer history [Table 6].

RESULTS

Statistical analysis

The information gathered on the basis of above observations was subjected to statistical analysis using GraphPad InStat. Software Version 3.10. As the criteria selected for analysis were nonparametric, hence "Paired *t*-test" was applied for statistical improvement analysis in the clinical features of *Amlapitta* in single group and "unpaired *t*-test" for statistical status of intergroup differences of clinical features. The results were interpreted.

Table 5: *Manasika Nidana* wise (mental factor) distribution

Manasika Nidana	Number of patients		Total (%)
	Group A	Group B	
Krodha	1	1	2 (6.66)
Soka	5	8	13 (43.33)
Chinta	5	5	10 (33.33)

Table 6: Risk factor wise distribution

Risk factors	Number of patients		Total (%)
	Group A	Group B	
NSAIDs	5	2	7 (23.33)
Previous ulcer	2	1	3 (10)
Smoking	1	2	3 (10)
Stress	7	3	10 (33.33)

NSAIDs: Non-steroidal anti-inflammatory drugs

The obtained results were interpreted as:

- No improvement: $P > 0.05$
- Improvement: $P < 0.05$
- Significant: $P < 0.01$
- Highly significant: $P < 0.001$

Relief observed in *Daha* and *Amlodgara* were 79.31% and 86.36%, respectively. Relief in *Shula* was 62.5%. Statistically, it is significant. Relief in *Chhardi* and *Avipaka* were 80% and 64.28%, respectively. Statistically, it is significant. Relief in *Aruchi* 75 % and result is significant ($P < 0.05$). While relief in *Utklesha* is 100%; this shows that there is a complete improvement in this symptom observed. Result was statistically highly significant ($P < 0.001$) [Table 7].

Relief in *Adhmana* was 81.81%, in *Vibandha* was 75%, and in *Bhrama* was 75%. All these results were significant. While relief in *Klama*is 66.66%, i.e., $P < 0.001$ this shows that it was extremely significant [Table 8].

As shown in Table 9, 96.42% relief was observed in *Daha* followed by 88.88% relief in *Amlodgara.* 72.27% change was observed in *Shula* followed by 58.33% relief in *Chhardi.* There was 60% relief in *Avipaka,* whereas *Aruchi* was relieved by 78.57%. 69.23% relief was observed in *Utklesha.* Changes in *Daha* and *Amlodgara* were extremely significant ($P < 0.001$). Relief obtained in *Shula and Chhardi* was significant ($P < 0.02$). Effect of intervention on *Aruchi and Utklesha* was highly significant ($P < 0.001$), whereas results obtained in *Avipaka were* significant ($P < 0.01$).

Results obtained in *Vibandha* (constipation) were not significant statistically ($P < 0.10$). Results obtained on *Bhrama* (vertigo) were not statistically significant ($P < 0.10$) [Table 10].

When comparison was drawn between Group A and Group B, Group B was found to be more effective in symptoms of *Aruci, Shoola, Daha*, respectively. However, these differences were found to be insignificant. Both groups were equally effective on providing relief from *Amlodgara* and *Avipaka.* Group A intervention was more effective in

Table 7: Effect on symptoms of Group A (*Khanda Pippali Avaleha*)

Chief complaints	Mean score		$\bar{X}$	%	SD	SE	*T*	*P*
	BT	AT						
Daha (*n*=13)	2.2308	0.4615	1.7692	79.31	0.725	0.2011	8.798	<0.001
Amlodgara (*n*=12)	1.833	0.25	1.5833	86.36	0.793	0.2289	6.917	<0.001
Shoola (*n*=9)	1.7778	0.6667	1.111	62.5	0.6009	0.2003	5.547	<0.001
Chhardi (*n*=9)	1.6666	0.333	1.333	80	0.866	0.288	4.618	<0.01
Avipaka (*n*=13)	2.1538	0.7692	1.3846	64.28	0.6504	0.1804	7.6752	<0.001
Aruchi (*n*=10)	2	0.5	1.5	75.00	1.291	0.6455	2.323	<0.05
Utklesha (*n*=12)	4	3	1.417	100	0.793	0.2289	6.1888	<0.001

BT: Before treatment, AT: After treatment, $\bar{X}$: Mean difference, %: Percentage relief, SD: Standard deviation, SE: Standard error

relieving *Chhardi*and *Utklesha*. However, the difference was found to be nonsignificant [Table 11].

When comparison was drawn between the Group A and Group B regarding the effect of treatment on the associated symptoms, the statistically significant difference was found to be insignificant. However, the intervention of Group A was found to be more significant in providind relief from all associated symptoms.

In Group A, only 7.69% (number = 1) patients showed relapse to moderate improvement after having marked improvement.

Table 8: Effect on associated symptoms (Group A)

Associated complaints	Mean score		$\bar{X}$	%	SD	SE	*T*	*P*
	BT	AT						
Adhmana (*n*=12)	1.8333	0.333	1.5	81.81	0.522	0.150	9.949	<0.001
Vibandha (*n*=10)	1.2	0.3	1.9	75	0.5676	0.1795	5.013	<0.001
Bhrama (*n*=5)	1.6	0.4	1.2	75.0	0.836	0.374	3.207	<0.05
Klama (*n*=12)	1.5	0.5	1	66.66	0.603	0.174	5.744	<0.001

BT: Before treatment, AT: After treatment, $\bar{X}$: Mean difference, %: Percentage relief, SD: Standard deviation, SE: Standard error

Table 9: Effect on symptoms of Group B (standard drug)

Chief complaints	Mean score		$\bar{X}$	%	SD	SE	*T*	*P*
	BT	AT						
Daha (*n*=12)	2.33	0.083	2.25	96.42	0.753	0.217	10.34	<0.001
Amlodgara (*n*=12)	2.25	0.25	2	88.88	0.852	0.246	8.124	<0.001
Shula (n=6)	1.833	0.5	1.33	72.27	0.816	0.333	4	<0.02
Chhardi (*n*=7)	1.714	0.714	1	58.33	0.8165	0.3086	3.240	<0.02
Avipaka (*n*=11)	1.818	0.727	1.090	60.0	0.943	0.284	3.833	<0.01
Aruchi (*n*=4)	1.556	0.333	1.222	78.57	0.441	0.417	8.315	<0.001
Utklesha (*n*=10)	1.3	0.4	0.9	69.23	0.5676	0.1795	5.013	<0.001

BT: Before treatment, AT: After treatment, $\bar{X}$: Mean difference, %: Percentage relief, SD: Standard deviation, SE: Standard error

Table 10: Effect on associated symptoms of Group B

Associated complaints	Mean score		$\bar{X}$	%	SD	SE	*T*	*P*
	BT	AT						
Adhmana (n=11)	1.45	0.36	1.09	75	0.539	0.162	6.70	<0.001
Vibandha (n=10)	1.4	0.8	0.6	42.85	0.843	0.266	2.25	<0.10
Bhrama (n=5)	1	0.4	0.6	60	0.547	0.244	2.44	<0.10
Klama (n=9)	1.44	0.77	0.66	46.15	0.5	0.166	4	<0.01

BT: Before treatment, AT: After treatment, $\bar{X}$: Mean difference, %: Percentage relief, SD: Standard deviation, SE: Standard error

Table 11: Comparison between group a and group b in terms of chief complaints

Chief complaints	Mean±SD		% Relief		Df=N1+N2−2	Unpaired *t*-test	*P* value	*P* value
	Group A	Group B	Group A	Group B				
Daha	1.7692±0.725	2.25±0.753	79.31	96.42	23	1.596	0.1241	>0.05
Amlodgara	1.58±0.793	2±0.852	86.36	88.88	22	1.250	0.2244	>0.05
Shoola	1.11±0.6009	1.33±0.816	62.5	72.27	13	0.6036	0.5565	>0.05
Chhardi	1.333±0.866	1±0.8165	80	58.33	14	0.7819	0.4473	>0.05
Avipaka	1.3846±0.6504	1.090±0.943	64.28	60	22	0.9025	0.3766	>0.05
Aruchi	1.5±1.291	1.22±0.441	75	78.57	6	0.4105	0.6957	>0.05
Utklesha	1.3±0.674	0.9±0.5676	100	69.23	20	1.487	0.1525	>0.05

SD: Standard deviation

One patient (7.69%) showed relapse to mild improvement after marked improvement. Rest 84.61% showed no increase in grading [Table 13].

In Group B, all patients showed relapse after having complete remission from the intervention and another 16.66% (number = 2) showed relapse from marked to mild improvement, one patient showed relapse from moderate to mild improvement (8.33%). Two patients were found no improvement after 1 month of intervention. Rest 58.33% showed no increase in grading.

DISCUSSION

Sex

In this study, maximum percentage of females were observed which approximate corresponds with data as per study conducted by B Benerson et al, Non- ulcer dyspepsia and peptic ulcer: the distribution in a population and their relation to risk factors observed the prevalence of non-ulcer dyspepsia more in females. The distribution in a population and their relation to risk factors observed the prevalence of nonulcer dyspepsia more in females. This study well correlates with above data. 53.33% patients who were female suffered from this disease because of their mental and physical stress, which is due to professional as well as personal responsibilities. Higher incidence in female is due to imbalance and irregularity in diet intake.

Agni

Nearly, 53.33% patients were having *Mandagni* [Table 4], whereas 46.67% patients were having *Vishamagni*. Main causes for the disease are improper diet, not following *AharaVidhiVisheshayatana, Viruddhahara,* and *Asatmyaahara* which is the main factor of impaired digestive function, i.e., *Mandagni*.[2]

Risk factor

About 33.33% patients are suffering from stress; 26.67% had history of consumption of NSAIDs [Table 6]. NSAIDs are the most common cause of peptic ulcer disease in patients without *Helicobacter pylori* infection. Topical effects of NSAIDs induce submucosal erosions. In addition, by inhibiting cyclooxygenase, NSAIDs inhibit the formation of prostaglandins.[7]

In a study conducted by Dr. Rafi Abul Siddique, the prevalence of acid peptic disease among the patients with abdominal pain - 88.3% had stress, anxiety, or tension which supported our study.[8]

Manasika Nidana

As per Table 5, 43.33% of patients were having *Soka* (grief), 33.33% of patients were having *Chinta* (worry, tension).[9] *Manasika Bhavas* (psychological factor) cause *Mandagni* (diminished metabolism) and *Ajirna* (indigestion) which were responsible for the aggravation of the disease process.[10]

Acid peptic disorder forms as a result of stress, a genetic predisposition to excessive stomach acid secretion and poor lifestyle habits. It was believed that such influence contributes to a build-up of stomach acids that erode the protective lining of the stomach.

Table 12: Comparison between Group A and Group B in terms of associated symptoms

Associated complaints	Mean±SD		% Relief		Df=N1+N2−2	Unpaired *t*-test	*P* value	*P* value
	Group A	Group B	Group A	Group B				
Adhmana	1.5±0.522	1.09±0.539	81.81	75	21	1.853	0.0780	>0.05
Vibandha	1.9±0.5676	0.6±0.843	75	42.85	18	4.045	0.0008	>0.05
Bhrama	1.2±0.836	0.6±0.547	75	60	8	1.342	0.2163	>0.05
Klama	1±0.603	0.66±0.5	66.66	46.15	19	1.372	0.1860	>0.05

Table 13: Follow up study

Relief (%)	Number of patient (%)			
	Group A		Group B	
	AT	After 1 month	AT	After 1 month
Complete resolution (100)			1 (8.33)	0
Marked improvement (76 to<100)	9 (69.23)	7 (53.84)	5 (41.66)	3 (25)
Moderate improvement (51 to<75)	3 (23.07)	4 (30.769)	6 (50)	4 (33.33)
Mild improvement (26 to<50)	1 (7.69)	2 (15.384)		3 (25)
No improvement (<25)				2 (16.66)

BT: Before treatment, AT: After treatment

Khanda Pippali Avaleha was found to be significant in providing percentage relief in symptoms: *Amlodgara* (Acid regurgitation), *Chhardi* (Vomiting), *Daha* (burning sensation), and *Utklesha* (Nausea) and in all associated symptoms. Relief *in Daha, Amlodgara* was found to be due to *Tikta-Kashaya Madhura Rasa* (Pungent, astringent, and sweet taste) having *Pitta Shamaka*, *Kapha-Vata Hara, Tridosha Hara* action.

Chhardi was found due to irritation of vagus nerve. The *Vidagdha Ahara* (undigested food) and *Kapha Dosha* were responsible for it. Most of the drugs of *Aushadha Yogas* have *Laghu* and *Ruksha Guna* which mitigate the *Kapha Dosha* of the body and thus relieve this symptom rapidly.

More significant relief was found in associated symptoms such as *Adhmana* (flatulence) and *Vibandha* (constipation) were due to *Agnideepak* (digestive property), *Mridurechana* (mild laxative), *Vatanulomana* (downward movement of Vayu), and *Pachana* (carminative) property.

However, standard drug (omeprazole) was found to be quite effective in providing immediate relief from symptoms such as *Daha, Amlodgara,* and *Shula* (pain). However, during follow-up after 1 month, there is reduction in percentage relief and relapse of symptoms occurs while treatment with ayurvedic palliative medicine more sustained relief was found.

CONCLUSION

Khanda Pippali Avaleha was proved to be quite promising treatment of *Amlapitta* as that of the standard drug. After 1 month of treatment, more sustained response was observed in patients treated with *Khanda Pippali Avaleha* studying on repeated application of these treatment procedures may be conducted to evaluate further. For better and more accurate results, this study should be conducted on the large sample so that new ayurvedic palliative drug can be arised as a new ray of hope in the management of *Amlapitta* without any complications and side effects.

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