

Randomized controlled clinical trial to evaluate the efficacy of *Eladi churna* in the management of urdhwag amlapitta with special reference to GERD

Research Article

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Abstract

Amlapitta is one of the most common diseases seen in society. The word Amlapitta is made up of Amla and Pitta. Acharya Kashyapa was the first person who described Amlapitta as a separate disease. Madhav Nidan, Bhavprakash, and Yogratnakara have also described it very well. The disease in which the sour quality of Pitta dosha aggravates and changes to extreme acidic sourness is called Amlapitta. Amlapitta is Annavaha Strotas Vyadhi (gastrointestinal disease), which is caused due to Agnimandya and vitiations of Pachaka Pitta. Urdhwag Amlapitta can be correlated with GERD. Gastroesophageal reflux disease (GERD) is one of the most common gastrointestinal diseases. It is defined on the basis of both esophageal and extra-esophageal symptoms and/or lesions resulting from the reflux of gastric contents into the esophagus. The sign and symptoms of Urdhwag Amlapitta (GERD) are Avipak (Indigestion), Klama (Tiredness), Utklesha (Nausea), Tikta amla udgar (Sour and bitter Belching), Gaurvata (Heaviness), Hruth Kantha Daha (Heart and Throat Burning), and Aruchi (Anorexia). In the present era, consumption of fast food, junk food, anxiety, and depression are the main causes of Amlapitta. In this clinical study, Eladi churna was used, which is described by Yogratnakar in Amlapitta chikitsa. A total of 70 patients were taken, which were divided into two groups of 35 patients for each group. Group A-Eladi Churna (Trial) and Group B-Amlapittapinashak yog as a control drug mentioned in Bhaishajyaratnawali.

Key Words: Urdhwag amlapitta, Ama, Pitta, GERD, Eladi churna.

Introduction

Ayurveda is known to be one of the oldest scientific medical systems in the world. The aim of Ayurveda is not only to treat the patient but to preserve and promote health. Nowadays lifestyles are completely changed. People are ignoring their health and food habits like irregular food intake, excessive use of spices, junk food, etc. All these are causative factors for Amlapitta. Psychological factors like anxiety, depression, and fear also play a major role in producing Amlapitta. Amlapitta is Annavaha Strotas Vyadhi (gastrointestinal disease), which is caused by Agnimandya (dyspepsia/weak digestive fire) and vitiations of Pachaka Pitta. The word Amlapitta is made up of two words: Amla and Pitta. There are two types of Pitta: Prakrut Pitta and Vidhghadha Pitta. Prakrut Pitta is Katu Rasa (pungent taste) and Vidghadha Pitta is Amla Rasa (sour taste). The disease in which the sour quality of Pitta dosha aggravates and changes to extreme acidic sourness is called Amlapitta. (1) Pathogenesis of Amlapitta involves three important factors, i.e., Agnimandya, Ama, and Annavahastrotodushti, along

with vitiation of Pitta and Kapha, leading to qualitative and quantitative changes in Pachak Pitta. Increases in Ama and Drava guna of Pachaka Pitta give rise to Amlapitta. Urdhwag Amlapitta can be correlated with GERD. Gastroesophageal reflux disease (GERD) is one of the most common gastrointestinal diseases. It is defined on the basis of both esophageal and extra-esophageal symptoms and/or lesions resulting from the reflux of gastric contents into the esophagus. GERD symptoms can be typical, such as heartburn and regurgitation, or atypical, such as chest pain, chronic cough, laryngitis, and hoarseness (2). The symptoms and signs of both diseases are nearly identical. The disease has been described in detail in classical Ayurvedic texts- Kashaya samhita, Yogratnakar, Bhaishajyaratnawali, etc. It is characterised by features like Avipak (indigestion), Klama (tiredness), Utklesha (nausea), Tiktaamloudgar (sour and bitter bleching), Hruth kantha daha (heartburn), Aruchi (anorexia), and Gauravta (heaviness) (1). In this clinical study, Eladi churna (3) was used, which is described by Yogratnakar in Amlapitta chikitsa. A total of 70 patients were divided into two groups, 35 patients for each group. Group A-Eladi Churna (Trial) and Group B-Amlapittapinashak yog as a control drug mentioned in Bhaishajyaratnawali (4).

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Historical Review

Acharya Kashyapa was the first person who described Amlapitta as a separate disease. He has

mentioned its Nidan (causes), Lakshana (symptoms), Samprapti (pathogenesis), and Chikitsa (treatment) in Khilasthan(5). Madhavakara also explained Amlapitta in detail. He has described two types of Amlapitta according to gati as Urdhwaga and Adhog Amlapitta(1). Bhavaprakash (6,7), Yogratanakar(2) also explained Amlapitta. Acharya Charak did not mention Amlapitta, but in sutrasthan and chikitsa sthan, the word Amlapitta is mentioned (8). In sushrut samhita the Amlika word used to describe Lavanarasa Atiyog, which is a symptom of Amlapitta.(9).

Aims and Objectives

Aim

To study the efficacy of Eladi Churna in the management of Urdhwag Amlapitta with special reference to GERD.

Primary Objective

To study the efficacy of Eladi Churna in the management of Urdhwag Amlapitta with special reference to GERD.

Secondary Objective

To compare the efficacy of Eladi Churna and Amlapitta Vinashak Yog in the management of Urdhwag Amlapitta with special reference to GERD.

Materials

- Patients: A total 70 patients were selected for this study. Patients were selected by a simple randomised method.
- Place of study: OPD and IPD of the Kayachikitsa Department of our college.
- Drugs:

Drug Formulation Details

Table no 1: Showing ingredient of Eladi churna

Drug	Latin Name	Ras (taste)	Virya (potency)	Vipaka	Guna (qualities)	Karma
Ela	<i>Elettaria Cardamomum Maton.</i>	Katu (pungent) Madhur (sweet)	Sheet (cold)	Madhur	Laghu(light), Snigdha (unctuousness)	Dipan, Pachan, Anuloman, Mukhshodhan
Aamalaki	<i>Emblica officinalis L.</i>	Amla(sour) Madhur, Kashay, Tikta, Katu,	Sheet	Madhur	Laghu, Ruksha	Tridosahar Deepan, Aampachan, Anuloman
Haritaki	<i>Terminila Chebula Retz</i>	Kashay, Madhur, Katu,	Ushna (hot)	Madhur	Laghu, Snigdha	Anuloman, Kaphpittanashak Deepan, Pachan
Vanshalochan	<i>Bambusa Arundinacea L.</i>	Tikta, Katu, Kashyay (astringent)	Sheet	Katu	Laghu, Ruksha(dry)	Vatapittashamak, Dipan, Hrydya, Pachan
Twaka	<i>Cinnamomum Zeylanicum. Blume</i>	Katu, Madhur	Ushna	Madhur	Laghu, Ruksha	Mukh durgandhihar, Dipan, Aampachan, Vatanuloman, Mukhshodhan
Pippalimul	<i>Piper Longum Linn</i>	Katu, Tikta (bitter)	Ushna	Katu	Laghu, Ruksha, Tikshna	Yakrututejjan, Truptighna, Dipan, Pachan

- Eladi churna (Trial Group) – Was Prepared in our college's Rasashastra Department.
- Amlapittavinashak yog (control group) – Was prepared in our college's Rasashastra Department.
- Analytical study- Eladi churna and Amlapittavinashak yog were authenticated and standardised as per API guidelines from the laboratory.

Methods

- Study design: Randomised single blind controlled clinical trial.
- Study population: Study was carried out on the patients suffering from signs and symptoms of Urdhwag amlapitta among those attending OPD and IPD of our college.
- Sample size: 70
- Sample technique: Simple random sampling technique (lottery method)
- Duration of study: 18 months.

Inclusion criteria

- Age group - 18-60 yr.
- Sex - both Male & Female.
- Patients fulfilling the diagnostic criteria which are based on sign and symptoms of Urdhwag Amlapitta.
- Patients willing for treatment with informed consent.

Exclusion criteria

- Patients aged below 18 years and above 60 years were excluded.
- Patients not willing for clinical trial
- Pregnant & lactating mothers.
- K/C/O- DM/HTN/CRF/CANCER.
- Any other addictions like chronic alcoholism induced hyperacidity.

Chandan	<i>Santalum Album</i> Linn	Tikta , Katu	Sheet	Katu	Laghu, Ruksha	Pittashamak, Aampachan, Dahshamak
Tamal	<i>Cinnamomum</i> <i>Tamala Nees</i>	Madhur, Katu Tikta	Ushna	Madhur	Tikshna ,Laghu Singdha	Anuloman, Dipan
Aakarakarabha	<i>Anacyclus</i> <i>Pyrethrum</i> Linn	Katu	Ushna	Katu	Laghu, Ruksha, Tikshna	Kanthaya, Uttejak
Sharkara	<i>Sugar</i>	Madhur				Dahshamak

Table no 2: Showing ingredient of Amlapittavinashak yog

Drug	Latin name	Rasa	Virya	Vipak	Guna	Karma
Pippali	<i>Piper longum</i> Linn	Katu	Anushan	Madhur	Laghu, Snighdha, Tikshna	Rasaya, Dipan
Madhu	Honey	Madhur Kashay	-	-	Yogvahi, Rochak, Laghu, Grahi	Pittanashak, Agnidipak

Assessment criteria

The improvements in the patients were assessed mainly on the basis of relief in signs and symptoms of the Urdhwag Amlapitta. For this purpose, the main signs and the symptoms were given gradations according to their severity, and all the parameters of assessment before, after, and follow up day were taken into consideration to assess the total effect of the treatment.

Subjective Criteria

- Avipaka (indigestion)
- Klama (tiredness)
- Utklesha (nausea)
- Tikta amla udgara (bitter and sour blenching)
- Gaurvata (heaviness)
- Aruchi (loss of appetite)
- Hrudh kantha daha (heartburn)

Grading and scoring

Table no 3: Showing grading and scoring

0	Normal / absence of sign & Symptoms
1	+ Mild (0-35%)
2	++ Moderate (35-70%)
3	+++ Severe (70-100%)

Criteria for overall effect of therapy

Table no 4: Tiktamloudgar (Bitter and sour blenching)

0	Absent
1	Sometimes during day
2	Small amount of fluid regurgitate to mouth
3	Severe, disturbing the patient.

Table no 5: Hrithkanthadaha (Heartburn)

0	Absent
1	Daha of mild degree in any area of Kanth, Udar, Ura, Kukshi.
2	Daha of Moderate degree in most area of Kanth, Udar, Ura, Kukshi
3	Daha of severe degree relieving after vomiting.

Table no 6: Avipak (Indigestion)

0	Absent
1	Unable to digest mild fatty food
2	Unable to digest 3 course of meal
3	Unable to digest food

Table no 7: Aruchi (Loss of appetite)

0	Absent
1	Tasteless, can take diet
2	Tasteless, can take little amount of diet
3	Tasteless, can't take regular diet

Table no 8: Klama (Tiredness)

0	Absent
1	Feeling of tiredness after exertion
2	Feeling of tiredness after normal work
3	Feeling of tiredness even at rest

Table no 9: Utklesha (Nausea)

0	Absent
1	Nausea after taking particular food
2	Nausea after taking all kind of food
3	Full day nausea not related to food

Table no 10: Gaurav (Heaviness)

0	Absent
1	Heaviness after taking more quantity of heavy food
2	Heaviness even after taking light food
3	Heaviness even after not taking any food

Table no 11: Overall assessment criteria - In response to treatment the overall effect will be categorised as below

0%	Unchanged
1-25%	Least improvement
26% -50%	Mild improvement.
51% -75%	Moderate improvement.
76% -100%	Marked improvement.

Table no 12: Treatment details

Group	Group A : Trial group	Group B: Control group
No. of patients	35	35
Treatment	Eladi Churna	Amlapittavinashak Yog
Dose	1gm BD	250mg BD
Route	Oral	Oral
Anupan	Koshan jal (Warm water)	Madhu (Honey)
Kalpna	Churna	Churna
Kaal	Twice a day after meal (Vyanodan)	Twice a day after meal (Vyanodan)
Duration	28 days	28 days
Follow up	7 th , 14 th , 21 th & 28 th day	7 th , 14 th , 21 th & 28 th day

Observation and Results

For this study, 70 patients were selected randomly for the study. Patients were selected as per inclusion and exclusion criteria. As grading used for assessment parameters were ordinal in nature, “wilcoxon Signed Rank Test” is used for intra-group comparison.(i.e. before and after treatment group) while for inter-group comparison ,(i.e. for comparing two groups with each other) “Mann-Whitney U test” is used. The level of significance is kept at 0.05%.

Distribution of patients according to Gender: In the control group, 23 patients (66%) were male , while 12 patients (34%) were female. In the trial group, 25 patients (71%) were male, while 10 patients (29%) were female.

Distribution of patients according to Diet: In the control group, 19 patients (54%) were on a mixed diet, while 16 patients (46%) were vegetarian. In the trial group, 17 patients (49%) were on a mixed diet, while 18 patients (51%) were vegetarian.

Distribution of patients according to Agni: In the control group, 22 patients (63%) were seen with Mandagni while 13 patients (37%) were having Vishamagni. In the trial group, 22 patients (63%) were seen with Mandagni while 13 patients (37%) were having vishamagni.

Distribution of patients according to Age: In the control group, 7 patients (20%) were between the ages of 21 –30 years, 13 patients (37%) were between the ages of 31 – 40 years, 13 patients (37%) were between the ages of 41 – 50 years, and the remaining 2 patients (6%) were between the ages of 51-60 years. In the trial group, 10 patients (29%) were aged between 21 – 30 years, 13 patients (37%) were seen with and age between 31 – 40 years, 6 patients (17%) were having aged between 41 – 50 years and remaining 6 patients (17%) were with aged between 51-60 years.

Table no 13: Showing statistical analysis

Symptoms	Group	Mean score		Mean	Median	T+	P Value	S.D.	S.E	U value
		BT	AT							
Avipak	Trial	1.457	0.2	1.257	1.00	435	<0.001	0.817	0.138	1048.0
	Control	1.514	0.714	0.8	1.00	371	<0.001	0.5314	0.089	
Hruthkanth-daha	Trial	1.486	0.171	1.314	1.00	518.5	<0.001	0.832	0.14	1086
	Control	1.514	0.543	0.971	1.00	351	<0.001	0.747	0.126	
Gauravta	Trial	0.829	0.114	0.714	1.00	276	<0.001	0.5725	0.096	1104
	Control	1.057	0.600	0.457	0.00	136	<0.001	0.5054	0.085	
Aruchi	Trial	1.143	0.143	1.00	1.00	300	<0.001	0.84	0.141	1171.5
	Control	1.429	0.629	0.8	1.00	378	<0.001	0.4728	0.079	
Klama	Trial	0.057	0.14	0.543	1.00	171	<0.001	0.5606	0.094	1114.5
	Control	1.057	0.743	0.314	0.00	66	<0.001	0.471	0.079	
Utklesha	Trial	0.886	0.114	0.771	1.00	253	<0.001	0.731	0.123	1090
	Control	0.943	0.514	0.429	0.00	120	<0.001	0.5021	0.084	
Tiktaamlo-udgar	Trial	1.514	0.2	1.314	1.00	528	<0.001	0.631	0.106	1058
	Control	1.543	0.571	1.314	1.00	435	<0.001	0.618	0.017	

Table no 14: Overall percent improvement

Parameter	Control Group	Trial Group
Avipak	74.29	82.86
Klama	31.43	51.43
Utklesha	42.86	62.86
Tiktoamloudgar	82.86	91.43
Hruthkanthdaha	74.29	91.43
Gauravta	45.71	65.71
Aruchi	77.14	68.57
Overall Average % increment	61.22571	73.47

In all parameters Eladi churna is significantly effective than Amlapittavinashak yog except Aruchi it is equally effective.

Discussion

Amlapitta is one of the important diseases of Annavaastrotas vyadhi (gastrointestinal disorder). Amlapitta is stated to be a disease due to Agnimandya, and disturbance to Agni caused by irregular diet and behavioural patterns as well as the involvement of mental stress and strain leads to the formation of Ama. Which combines with Vidhgadha Pitta from Aamashay (stomach) and turns into shukta-paka and manifests

clinically. The clinical definition of both diseases has similar symptoms like Tikta-amloudgar (bitter and sour taste), hrutkanthadaha (heartburn), Avipak (indigestion), Utklesha (nausea), Aruchi (loss of appetite), and Gauravta (feeling heaviness in the body).

Probable mode of action of drug Group A - The present study was conducted among 35 patients. The patients were assessed on various parameters to obtain the effect of therapy. All the clinical signs and symptoms were assessed on the basis of scores given to them before and after treatment. Eladi churna was given for 28 days. Significant relief was observed in the symptoms of Urdhwag Amlapitta like Avipak, Tikta-amloudgar, etc. after 28 days of treatment with Eladi churna. The Doshas involved in the Amlapitta are Vata, Pitta, and Kapha. In the Eladi churna, the majority of the drugs have Madhura, Tikta, Katu, Kashay Rasa, Madhura & Katu Vipak, Sheeta-ushna Virya (potency), Ruksha, Laghu, Snigdha Guna & Tridosha Shamak Property. Utklesha and Trishna in Amlapitta are relieved by the Chhardi Nigrahana and Trishna Nigrahana (reduce thirst) property of Chandan, Vanshalochan. The Chandan and Sharkara properties relieve Hruthkanthdaha. Ela, Haritaki, Pippalimul, Amlaki, Twak, Tamal have Deepan, Aampachan property helps to convert Sampitta into Niram pitta, improves digestion and reduces Avipak, Gauravta, and Aruchi. All these Dravya also have Anuloman property and may act on Vimarg-gaman strotodushti, which may be the causative factor in the breakdown of the pathogenesis and relieve Tiktamloudgar in Urdhwag Amlapitta. Due to Ushna Virya of Haritaki, Tamal, and Twak, it does not allow Vata Prakopa, so it relieves Adhmana (bloating). Haritaki, being Mrudu Rechaka, controls Vibandha. Amlaki and Haritaki are Rasayana Dravya. Due to its Rasayana Property, all Dhatus get adequate nourishment, and thus Dhatu Prasadana occurs and relieves Klama. Eladi churna given with Koshna Jala (warm water) also acts as Deepan and Pachan. In Eladi churna, maximum ingredients have been well indicated in Pitta predominant pathologies, Due to this property, it breaks the Samprapti (pathogenesis) of Amlapitta and normalises the state of Agni (digestive fire). Doing the function of Strotovibandhanasana and action against Pitta, it is effective on Pitta and Mandagni, and provides good results in all signs and symptoms. Jatharagni is thus regulated, preventing excessive Pitta growth and accumulation.

Probable mode of action Drugs Group B

Amlapittavinashak yog contains Pippali churna along with Madhu. Pippali is Katu Rasa, Madhur Vipak, Ushna Virya, Laghu, Tikshna, and Snigdha Guna in nature. Pippali does Deepan (increase digestion), Pachan, and Rasayan (rejuvenation) karma. All these properties of Pippali help to convert sampitta into niram pitta and normalise Agni. Relieves Avipak, Tiktamloudgar, Aruchi, and Gauravta. Pippali's Rasayan

karma aids in the relief of klama. Madhu also has deepan, pachan, and yogvahi property. In this way, Amlapittavinashak yog helps to breakdown the samprapti (pathogenesis) of Amlapitta.

Conclusion

On the basis of the study of review of literature, observations noted during the study, findings collected after the clinical trial, and the results obtained after statistical analysis, the following conclusions are drawn. Urdhwag Amlapitta (Gastroesophageal Reflux Disease) is a commonly occurring disease.

Clinical manifestations of Urdhwag Amlapitta are very similar to those of Gastroesophageal Reflux Disease. Vyasana (addiction) like tea, coffee, Amla, katu, and Lavan Rasatmak Aahar were the causative factors of disease. In the study population, a number of patients are males. It is seen that males are more prone to Urdhwag Amlapitta. Mandagni and mixed diets are also causative factors for Urdhwag Amlapitta. The middle age group is also affected. Eladi churna has shown significant results in Urdhwag Amlapitta (Gastro Esophageal Reflux Disease) and it is effective in reducing symptoms like Aruchi, Avipak, Klama, Utklesha, Tiktamloudgar etc. There were no side effects observed during the period of study.

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