

## Evaluation of efficacy and safety of Gas-O-Fast (Ajwain) in Amlapitta

### Research Article

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### Abstract

Modern era's, changing lifestyle along with changing food habits and depending upon one's body constitution *Amlapitta* is one of the most common symptom (disease) seen in the society. *Amlapitta* is very distressing due to its chronic, relapsing and remittent nature. 'Hurry', 'Worry', and 'Curry' are the three main reasons for the disease. The industrialization, stress due to work, lack of exercise and faulty food habits leads to disturbance of *Agni* or metabolism which leads to many disorders, *Amlapitta* is one of them. Acidity refers to set of symptoms caused by an imbalance between the acid secreting mechanism of stomach and the protective mechanisms of gastric mucosa that ensure their safety. When due to some reason, there is excess production of acid by acid secreting glands of stomach, it results in condition known as Acidity. Acidity tends to have a much higher incidence in highly emotional and nervous individuals. Faulty lifestyle undoubtedly has a much higher role in this disease. Non-steroidal Anti Inflammatory Drugs (NSAID's) also predispose to gastric acidity. Prolonged acidity is responsible for symptoms like Dyspepsia, Heartburn and if not taken care of, the erosion of the lining of stomach or intestines result with the formation of Ulcers. Current research proposal is small step to explore evidence based therapeutic potential of Ayurvedic herbal formulation. Present short term clinical trial was designed to evaluate efficacy of Gas-O-Fast (Ajwain), when used in a dose of 3 sachet /day in volunteers. Drug was given to the patients of dyspepsia for 30 days. It is evident that improvement in symptoms of *Amlapitta* (Non ulcer dyspepsia) was statistically highly significant without any side effects/ toxic effects of formulation.

**Keywords:** *Amlapitta*, Acidity, Gas-O-Fast (Ajwain), Non ulcer dyspepsia.

### Introduction

*Amlapitta* is the disease of *Annavaha Srotas*.(2) *Amlapitta* is one of disease due to *Agni Vaikritya* leading to production of *Ama*. *Agni* and *pitta* are the main factors responsible for digestion, due to their abnormality, food is not properly digested and produces the *Ama*, which is acidic in nature. *Annavisha* produced due to *Ajirna* when mixes with *Pittadi Dosh*, lodges in *Aamashaya* and produces the *Amlapittadi* diseases(2). Person gets various symptoms including *Amla udgara* (sour and bitter eructation), *Utklesha* (nausea) and *Udar Adhmana* (abdominal distension) etc. This syndrome is known as *Amlapitta*(*Ma. Ni. 51/2*). (1,5)

This is basically a disease of gastro-intestinal tract and due to abnormal secretions of gastric and pancreatic enzymes it has been described as acid peptic disorder.(8) *Amlapitta* can be linked to wide spectrum of diseases like Acute Gastritis, Non-Ulcer Dyspepsia, Acid Peptic disorder, Gastro-esophageal Reflux disease and Achlorhydria. Peptic ulcers have similar symptoms related to *Amlapitta*. But the patho-physiology and

histopathology said that ulcers can't be included in *Amlapitta*, rather it may be a complication of *Amlapitta*. So, the acid peptic disease without peptic ulcer can be included in *Amlapitta* i.e. Non-Ulcer Dyspepsia. It is a common complaint of patients visiting OPD in hospital set up. Functional or idiopathic dyspepsia commonly occurs as a chronic digestive disorder affecting 20-40% of general population.(9) This condition is characterized by a recurring variable cluster of upper abdominal symptoms associated with food intake for which no evidence of organic disease can be found. This includes a variety of upper gastrointestinal symptoms like epigastric / retrosternal burning sensation, sour eructation / belching, indigestion, nausea, vomiting and distension of abdomen. (7,9)

The gastric acid hyper secretion (Acidity) is one of the probable cause of dyspepsia. This can be caused by an imbalance between the acid secreting mechanism of stomach and the protective mechanism of gastric mucosa that ensure their safety of gastric mucosa. Incidence of this disease is more in highly emotional and nervous persons and individuals with faulty dietary habits e.g. fast foods and spicy foods. Indiscriminate use of several therapeutic agents like steroids, NSAID's, addiction to smoking, alcohol, taking tea and coffee several times are chiefly associated with this disease. These faulty dietary habits predispose individuals for hyperacidity.(7)

Though in modern medicine, plenty of new drugs are available to manage non-ulcer dyspepsia but all the drugs provide only symptomatic relief and none

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of them possess curative potentials. As these drugs are required to be consumed for a longer duration, so a lot of untoward effects are also inevitable. Hence in order to overcome these issues present study was planned to explore the efficacy of very simple, safe and cost effective herbal formulation to counteract the symptoms of *Amlapitta*. **Gas-O-fast (Ajwain)** a preparation prepared by M/S COPMED PHARMACEUTICALS PVT. LTD. which contains Svarjiksara (shudh), Nimbukamlam (Shushkam), (3) Ajwain and Excipients (Saccharin Sodium, Permitted Sweetener, Black salt, Permitted Colour) is used to relieve the symptoms of *Amlapitta*. Drug was given to the patients of *Amlapitta* for 30 days, it proved highly effective and no untoward effect is noted.

### Aims and Objectives

1. To evaluate the efficacy of Gas-O-Fast (Ajwain) in the management of *Amlapitta*.
2. To evaluate the safety of drug.

### Material and Method

The study was conducted in compliance with good clinical practice (GCP) guidelines and other applicable regulations.

### Selection of the Patients

A total of 30 patients were assessed of *Amalpitita* (Non ulcer Dyspepsia) fulfilling the diagnostic criteria having frequent complaints of dyspepsia irrespective of the cause, were registered from hospital wing of Kayachikitsa, Rajiv Gandhi Govt. P.G. Ayurvedic Hospital, Paprola Distt. Kangra H.P.

Trial patients of either sex were selected between age group of 18-70 years. Routine blood examinations (Hb<sub>gm</sub>%, TCL, DLC, ESR, FBS & RFT) were carried out in order to rule out any other pathology and monitor normal values of blood during trial period. Trial Subjects were detailed about nature of trial and informed consent was obtained.

**Table no. 2-** Each 5gm of sachet contains -

Sr. No	Drug	Latin name	Part used	Dose/sachet	Ref. Book Page no.	Guna Karma
1.	Svarjiksara (Shudh)	-	Churna	2.68 gm	Ras Taringini P-313-315	Pachaka, Deepana, Amlapitta Shamaka
2.	Nimbu kamlam (Shushkam)	<i>Citrus medica</i> L.	Fruit extract	2.24 gm	Ras taringini P- 316	Pachaka, Deepana, Amlapitta Shamaka
3.	Ajwain	<i>Trachyspermum ammi</i> Sprague.	Seeds	104 mg	Bhavprakasha Nigantu	Pachaka, Deepana, Amlapitta Shamaka
4.	Excipients: Saccharin Sodium, Black salt, Permitted sweetener, Permitted color				Indian Pharmacopeia	

### Period of Clinical Study

Commencement of trial : January 2015  
 Completion of trial : March 2015

### Inclusion Criteria

- Patients in the age group between 18 to 70 years of either sex.
- Patients able to provide informed consent.
- Patients were included on the basis of signs and symptoms of *Amalpitita* (Non ulcer dyspepsia) epigastric pain, burning sensation over epigastrium/retrosternal region, sour/ bitter eructation, nausea, vomiting, indigestion and abdominal distension.

### Exclusion Criteria

- Patients not willing for the trial or not ready to give informed consent.
- Patients with Peptic ulcer disease, IBS and past history of gastric surgery.
- Patients having malignancy, hypertension, cardiac problem, hepatic disorders, renal disorders, uncontrolled diabetes mellitus and other co-morbid diseases.

**Table no. 1:** Trial Drug “Gas-o-Fast (Ajwain)” and its administration

Formulation Name	Gas-o-Fast (Ajwain)
Pharmaceutical form	Powder
Dose	1 sachet in a glass of cold water
Route of administration	Oral
Frequency of administration	Twice a day and one as when required
Duration of administration	30 days
Ingredients	In table below
Storage	Moisture free environment

### Constituents:

The trial formulations contained following herbs and in the quantity mentioned. The formulation was prepared by M/S COPMED PHARMACEUTICALS PVT.LTD.

## Groups

The study was done in single trial group. It was open trial with voluntary participation of patients.

## Criteria of Assessment

Scoring system was adopted for assessment of various subjective features:

1. Daha (Epigastric & retrosternal burning)	Grade
No daha	0
Mild degree	1
Moderate degree relieved by milk, antacid	2
Severe degree involving hrita, kantha & relieved	3
After digestion of food & vomiting severe degree not relieved at all	4
2. Amla udgara (Bitter eructation)	
No amla udgara	0
Sometimes during day	1
Moderate degree	2
Severe degree disturbing patients daily routine	3
Small amount of fluid regurgitates to mouth	4
3. Utklesha (Nausea)	
Absent	0
Occasional desire to vomit	1
Frequent desire to vomit	2
Continuous desire to vomit	3
Continuous desire to vomit with profuse water brash	4
4. Avipaka (Indigestion)	
No indigestion	0
Occurs 2-3 times/week	1
Occurs daily but not severe	2
More than 2-3 ajirna ahara lakshna	3
Severe indigestion which does not subside without medicine	4
5. Chhardi (Vomiting)	
No vomiting	0
Feels sense of nausea and vomits occasionally	1
Frequency not more than 2-3 per week	2
Frequency between 4-6 per week and comes whenever	3
Pain is aggravated and Frequency is daily	4
6. Udar adhman (Flatulence)	
Absent	0
Occasional feeling of distension of abdomen	1
Moderate discomfort	2
Frequently distended abdomen	3
Continuously distended abdomen	4

## Statistical method used

t-test (IBM SPSS STATISTICS 20)

## Results and Observation

30 Patients were registered and all turned for follow up after 30 days. As per assessment criteria out of 30 patients, 15 patients showed complete, 7 patients showed moderate and 3 patients showed mild improvement in symptoms whereas 5 patients showed no improvement. Statistical analysis showed most of the variables kept in assessment criteria had statistically significant improved ( $p < 0.001$ ). The patients of all ages and both the sex groups reported improvement in their complaints. No side/adverse effect of the therapy was reported in any patient.

### Symptom wise details-

#### 1. Daha (Epigastric & retrosternal burning)

Mean Score before treatment was 3.1 which fell to 0.7 giving improvement of 74.19% which was statistically highly significant with t value of 19.3 and  $P < 0.001$ .

#### 2. Amla udgara (Bitter eructation)

Mean Score before treatment was 2.33 which fell to 0.7 giving improvement of 66.9% which was statistically highly significant with t value of 9.56 and  $P < 0.001$ .

#### 3. Utklesha (Nausea)

Mean Score before treatment was 2.93 which fell to 1.70 giving improvement of 41.9% which was statistically highly significant with t value of 9.2 and  $P < 0.001$ .

#### 4. Avipaka (Indigestion)

Mean Score before treatment was 2.93 which fell to 2.70 giving improvement of 7.84% which was statistically insignificant with t value of 10.283 and  $P > 0.05$ .

#### 5. Chhardi (Vomiting)

Mean Score before treatment was 2.16 which fell to 2.03 giving improvement of 6.01% which was statistically insignificant with t value of 1.68 and  $P > 0.05$ .

#### 6. Udar adhman (Flatulence)

Mean Score before treatment was 2.13 which fell to 0.53 giving improvement of 75.11% which was statistically highly significant with t value of 6.24 and  $P < 0.001$ .

**Table no. 3 Assessment of Patients: (Symptomatic improvement)**

Sr. No.	Assessment criteria	No. of Patients	Improvement				
			No.	Mild	Moderate	Complete	% Relief
1	Daha (Epigastric & retrosternal burning)	27	4(15%)	3	5	15	85%
2	Amla udgara (Bitter eructation)	28	4(14%)	4	6	14	86%
3	Utklesha (Nausea)	22	4(18%)	1	5	12	82%
4	Avipaka (Indigestion)	19	6(31%)	4	9	-	69%
5	Chhardi (Vomiting)	14	6(42%)	3	5	-	58%
6	Udar adhman (Flatulence)	23	4(17%)	3	4	12	83%

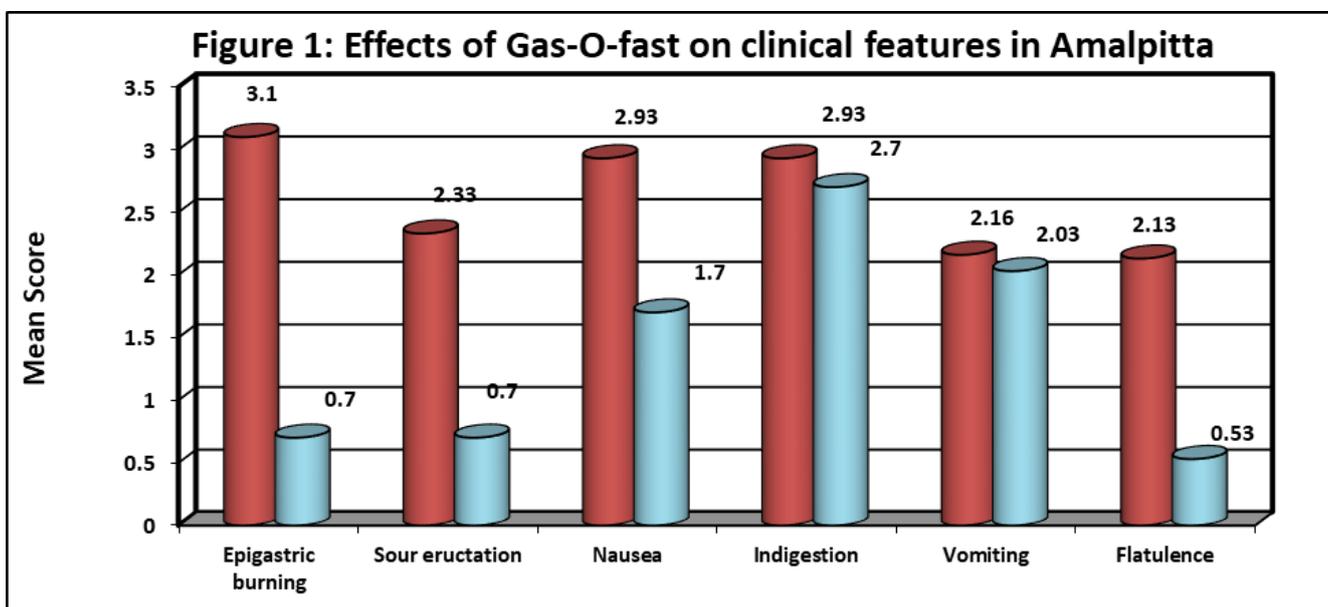
**Table no. 4 Effect of Gas-O-fast (Ajwain) on clinical features of Amalpittha in 30 days**

Sr. No.	Assessment Criteria	Mean		% Diff.	S.D±	S.E ±	't'	p
		BT	AT					
1	Daha (Epigastric & retrosternal burning)	3.1	0.7	74.19	0.66	0.12	19.3	<0.001
2	Amla udgara (Bitter eructation)	2.33	0.7	66.95	0.89	0.16	9.56	<0.001
3	Utklesha (Nausea)	2.93	1.70	41.9	0.72	0.13	9.2	<0.01
4	Avipaka (Indigestion)	2.93	2.70	7.84	0.50	0.09	2.53	>0.05
5	Chhardi (Vomiting)	2.16	2.03	6.01	0.43	0.07	1.68	>0.05
6	Udar adhman (Flatulence)	2.13	0.53	75.11	1.40	0.25	6.24	<0.001

BT: Before treatment; AT: After treatment; % Diff.: Difference of mean; S.D: Standard deviation; S.E: Standard Error

**Table 5: Overall Effect of Therapy**

Overall Effect of Therapy	No. of patients	% Relief
Complete Improvement	15	50
Moderate Improvement	7	23.3
Mild Improvement	3	10
No Improvement	5	16.7



## Discussion

Most of patients reported relief in symptoms of *Amalpitta*. Symptomatic relief of burning sensation was reported by the patients after 2<sup>nd</sup> dose of the drug and at the end of 4<sup>th</sup> week there were few negligible symptoms of dyspepsia. The relief in epigastric burning, sour eructation, nausea and flatulence was remarkable. The patients of all ages and both the sex groups reported relief in their complaints. It is evident that improvement in symptoms of *Amalpitta* (Non ulcer dyspepsia) was statistically highly significant without any side effects/toxic effects of formulation.

*Pathya* and *Apathya* are very important factors in the management of gastro intestinal disorders. The patients were strictly asked to modify their dietary habits about do's and don'ts in relation to Ahara and Vihara during clinical study, which may have great influence in relief of symptoms.(12) Most of the ingredients of trial drug have deepana, pachaka and amlapitta shamaka properties.(5) As nonfunctioning state of *Agni* is also responsible for illness which is corrected with deepana and pachaka guna of drugs. Rastaringini described the properties of Svarjiksara and Nimbukamlam Svarjiksara. Svarjiksara has Amalpitta and amla udgara shamaka properties with cold water. Nimbukamlam Svarjiksara alleviates bitter eructation and improving digestive power.(2) The presence of Svarjiksara and Citrus medica in drug has probably helped in neutralizing the gastric acid and thereby relieving the symptoms of non-ulcer dyspepsia.

*Trachyspermum ammi* (Ajwain) increases the secretion of gastric acid and also enhance the activity of digestive enzymes. It also has antiulcer property. The seeds contain 2-4.4% brown coloured oil, thymol the main constituent of oil used in gastrointestinal ailments. The seeds are quite effective for digestive problems like indigestion, acidity, bloating, flatulence and stomach ache. The traditional therapeutic uses of *Trachyspermum ammi* include galactagogue, stomachic, carminative, expectorant, antiseptic and antimicrobial. (10)

## Conclusion

From the above observations and discussion, it can be concluded that, Gas-O-Fast Ajwain is found to be very effective in the treatment of Amalpitta (Non ulcer dyspepsia). The present study emphasizes the effectiveness of GAS-O-FAST AJWAIN in the patients of Amalpitta (Non ulcer dyspepsia). Dyspepsia of recent onset and chronic nature in elderly patients needs to be

evaluated and investigated completely. Remarkable relief is noted in epigastric burning, sour/ bitter eructation, nausea and flatulence. The drugs used in this formulation also help in improving digestion and metabolism by their well-known effect at the level of agni (~digestive fire) thus targeting the root cause of various gastrointestinal disorders.

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