

Safety and efficacy study of Ulsant tablet in patients with hyperacidity (Amlapitta)

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Abstract

Hyperacidity (Amlapitta) is one of the most common disorder. It is observed by excess production of gastric acid in stomach. It is generally imbalance between offensive parameters like gastric acid and defensive factors like mucin bicarbonate secretions. Over the counter products aim at neutralizing gastric acid rather than the root cause. Ayurvedic preparations has an solution to amlapitta. It not only neutralizes acid secreted but also improves defensive properties of stomach. Once such combination is Ulsant tablets. Acid neutralizing capacity and buffering capacity was conducted in vitro. The aim of the present study was to find out safety and efficacy of Ulsant tablet. In present study total 35 patients were taken. Patients were advised with Ulsant tablet 2 tab twice a day for 45 days. Results shown significant positive results with respect to acid neutralizing capacity, buffering capacity and clinical symptoms.

Keywords: Hyperacidity, Ulcer, Ayurveda, Ulsant, Natural.

Introduction

Amlapitta is considered as one of the common disorder in the entire world. It is the imbalance between the normal physiologic process, leading to decrease in defensive factors and increase in offensive factors. There are many reasons behind the imbalance mainly NSAID (Non-steroidal anti-inflammatory drugs), Alcohol, Stress and H pylori infection. Urbanization together with changed lifestyle and intake of unwholesome spicy foods are also one of the cause for gastrointestinal disorders. All the major reasons causes increase in gastric secretions and decrease in gastric mucus secretion. There are two main approaches for treating Hyperacidity (amlapitta). The first deals with reducing the production of gastric acid and the second deals with re-enforcing gastric mucosal protection. Antacids and Proton pump inhibitor are widely prescribed medicines. Reports on clinical evaluation show the incidence of relapse and adverse effects like arrhythmias, impotence. Many bacterial species do not survive at pH levels below 4, hence acidic gastric environment is considered the most important barrier against colonization and infection by ingested bacteria in food we eat. Hence long term acid suppression increases risk of enteric infection and invariably, results in overgrowth of aerobic bacteria. Long term acid suppression may lead to gland atrophy, chronic achlorhydria and risk of gastric cancer leading to more of erosions.

For several decades the adage 'no acid – no ulcer' and drugs used to reduce acid secretion have dominated the pharmacological basis of ulcer therapy. Due to extensive research, treatment for gastric ulcer is now aimed at 'no mucosal damage - no ulcer'. Gastric mucus and mucosal bicarbonate secretion is considered as the most important defense mechanism for the prevention and healing of gastric ulcer. Ayurveda the oldest system of medicine provides leads to find therapeutically useful compounds from plants. It uses extensively time tested herbs in correct combination to treat various diseases. These herbs combination are complex mixtures of compounds and no single compound is thought to provide the desired activity. Some compounds produce the

desired therapeutic actions, while others reinforce the same and yet others are considered to neutralize and counteract any possible side effects. The combination of traditional and modern knowledge can produce better drugs to treat hyperacidity and gastric ulcer. One such combination is Ulsant tablets. Ulsant tablets is the combination of key ingredients such as Amalaki, Yashtimadhu, Shatavari, bhingraj, Neem, Gaduchi and others. Hence it was decided to conduct safety and clinical study of the same.

Aims and Objectives

Safety and Clinical study of Ulsant tablet in patients with Hyperacidity (Amlapitta)

Materials and Methods

In-vitro assays

Acid neutralizing activity: Different concentration of Ulsant tablet was taken, powdered and 70ml of water was added. After one minute 30 ml of 0.1N Hydrochloric acid was added to above solution and mixed for 15 mins. Later 3 – 5 drops of phenolphthalein solution is added and mixed. Excess of hydrochloric acid was titrated with 0.1 N sodium Hydroxide. The moles of acid neutralized is calculated as mentioned in

Buffering capacity

Ulsant tablet was finely ground and 25 ml of 0.1N hydrochloric acid was added with constant stirring. The pH of the solution was determined at regular interval, till pH below 2.75 was reached which shows the buffering power of tablet.

Sample size

35.

Study conducted

May, 2019 and ended on Sep, 2019.

Study duration

45 days, Follow up every 15 days till end of the study.

Drug formulation

Ulsant Tablets 2 bid.

Site of study

Yash clinic and research center

Screening and criteria for assessment of patients: Clinical symptoms for assessment

1) *Avipaka* (Indigestion), 2) *Utklesha* (Nausea), 3) *Vamana* (Vomiting), 4) *Tiktoamlogara* (Acid eructation), 5) *Hritkanthadaha* (Heart Burn), 6) *Aruchi* (Anorexia), 7) *Udarashoola* (Abdominal pain), 8) *klama* (tiredness). The assessment progress was noted after every 15 days till 45 days based on the above criteria. Grade points were assigned before and during the treatment as follows:

Severity	Grade	Grade points
Normal	G0	0
Mild	G1	1
Moderate	G2	2
Severe	G3	3

Inclusion criteria

1. Age-20 to 60 yrs
2. Both sexes
3. Mentally stressed and strained
4. Spicy and oily food in takers
5. Patients with classical symptoms of *Amlapitta*.
6. Patients who were co-operative and ready give written consent.

Exclusion criteria

1. Below 20yrs and above 60 yrs
2. Pregnant and lactating
3. Cancer of stomach

Table 3: Sex wise distribution

Sex of Patients	Male – 60% Female – 40 %
Age	33% - Between 20 - 29 years 27% - Between 30 - 39 years 20% - Between 40 - 49 years 20% - Between 50 - 60 years
Area of Living	57% - Urban area 43% - Rural area
Chronicity	60% <2 year
Nature of <i>Udarashoola</i>	40% Recurrently burning
Family history	77.5% Present
Habitat	77.5% <i>Anupa</i>
Nature of work	37.5% Service

Table 4: Grade wise relief in different sign & symptoms with Ulsant tablets treatment after 15, 30 and 45 days

S. No.	Sign and Symptoms	Grading from 0 to 5 (Normal to Severe)			
		Before treatment	After treatment 15 days	After treatment 30 days	After treatment 45 days
1	<i>Avipaka</i> (Indigestion)	3	2	1*	0*
2	<i>Klama</i> (Tiredness)	2	1	0*	0*

4. Cholecystitis
5. Barrett's oesophagus

Statistical assessment of results

Statistical T –test was applied before and after the treatment. The mean \pm SD before treatment of each sign and symptoms was compared with after 15days, 30 days and 45 days of treatment in each group. P value • P > 0.05 - Not significant or not quite significant • P < 0.05 – Significant • P < 0.01 - Very significant • P < 0.001 - Highly significant

Results**Table 1:** Acid neutralizing capacity of Ulsant tablet

Tablet Concentration in mg	Acid neutralizing capacity
100	23.00
250	23.20
500	24.30
1000	26.20
1500	27.80

Table 2: Buffering capacity of Ulsant tablet

Time in min	pH
0.0	2.44
0.5	2.98
2.0	3.09
4.0	3.40
6.0	3.41
8.0	3.50
10.0 – 20.0	2.32

Buffering capacity of Ulsant tablet lies in the range of 10.0 – 20.0 minutes.

3	Utklesha (Nuasea)	4	3	2.5	1*
4	Vamana (Vomitting)	3.5	2.5	1.0*	0*
5	Aruchi (Anorexia)	4.5	4	2.5	1*
6	Hritkanthadaha (Heart burn)	5	4	2.5*	1.5*
7	Tiktoamlodgara (Acid Eructation)	5	4	2.5*	1.5*
8	Udarashoola (Abdominal Pain)	4	3	2	1*

‘*’ – Indicates significance as compared to before treatment with $p < 0.05$.

Table 5: Showing the percentage of relief in different sign & symptoms with Ulsant tablets treatment after 15, 30 and 45 days

S.No	Sign and Symptoms	After treatment 15 days	After treatment 30 days	After treatment 45 days
1	Avipaka (Indigestion)	33.33	66.66	100.00
2	Klama (Tiredness)	50.00	100.00	100.00
3	Utklesha (Nuasea)	25.00	37.50	75.00
4	Vamana (Vomitting)	28.57	71.52	100.00
5	Aruchi (Anorexia)	11.11	44.44	77.77
6	Hritkanthadaha (Heart burn)	20.00	50.00	70.00
7	Tiktoamlodgara (Acid Eructation)	20.00	50.00	70.00
8	Udarashoola (Abdominal Pain)	25.00	50.00	75.00
9	Avrage relief in %	26.62	58.76	83.47

Discussion

As per United States Pharmacopeia (USP) No. 23 minimum acid neutralizing capacity for any antacid should not be less than 5.0. Ulsant tablet shows good Acid neutralizing activity. Acid neutralizing capacity of Ulsant tablets increases with the increase of the dose. Buffering capacity of Ulsant tablets was between 10 – 20 mins, which indicates it can keep neutralizing acid secretion upto 20 mins. Thereafter acid secretion would be in normal range.

Out of 35 patients, 30 patients completed the study. Ulsant tablet with the dose of two tablets two times a days showed marked improvement in the patients symptoms like *Avipaka*, *Klama*, *Utklesha*, *Vamana*, *Aruchi*, *Hridakanthadaha* and *Udarashoola*. Treatment with Ulsant tablet showed average 26.62 % improvement after 15 days, 58.76% after 30days treatment and 83.47% after 45 days treatment. All the ingredients of Ulsant tablets are *Pittasamaka* and *Deepan* in nature. The unique combination of Ulsant tablets neutralizes excess of gastric acid and regulates further secretion. Ingredients like *Yashtimadhu*, *Shatavari*, *Nimba* stimulates mucin bicarbonate secretions thereby strengthening defensive system. *Dhanyak*, *Kapurkachli* and *Nishottar* normalizes peristalsis and thus prevent reflux esophagitis. *Bhringraj* and *Amlaki* are potent antioxidant and anti-inflammatory plants. *Guduchi* widely known as *Amrita* is reported to have anti-stress and immunomodulatory activity, which helps in strengthening mucosal defense system.

Conclusion

The above studies implies that Ulsant tablet can be considered as an effective for treatment of *Amlapitta* (GERD).

Source of Funding

None.

Conflict of Interest

None.

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