A Clinical Study of Satavari Ghrita and Its Efficacy in the Management of Amlapitta

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Conflicts of interest: None to declare

Abstract

Amlapitta is a burning problem due to irregular and improper diet and dietetics, busy and stressful life style. Amlapitta includes Acid peptic disorders (APD)- gastroesophageal reflux disease (GERD), Peptic ulcer diseases (PUD), dyspepsia and functional disorder of GI tract. In spite of voluminous works done on Amlapitta and its management in Ayurveda, it still remains a common serious problem leading to complications. Therefore, in the present research work, Satavari ghrita was selected to evaluate its efficacy on scientific line to counter or reduce the symptoms of Amlapitta. Total 40 patients were randomly selected and divided into two groups. Group A-Total 20 patients in group A were registered and managed with Satavari Ghrita (Trial Drug). Group B- In these group 20 patients were registered and managed with Cow's Ghrita (Control Drug). The duration of trial was 30 days .Follow up every 15 day's period till the completion of therapy. The effect of Satavari ghrita is highly significant in case of patients of chronic condition as compared to acute condition of the disease.

Keywords: Amlapitta, Ayurveda, Acid peptic disorders, Dyspepsia, GERD.

1. Introduction

Amlapitta is a burning problem of the mankind due to irregular and improper diet and dietetics, busy and stressful life style. It is a very common disorder of Annavaha srotasa caused by Vidagdha Pitta with features like, Abipaka (indigestion), klama (fatigue), Utklesha (nausea), Tikta-Amlodgara (sour or bitter eructation), Gourava(heaviness), Hritkanthadaha (heart burn), Aruchi (anorexia) etc.[1] It classify into two head. In case of Adhaga Amlapitta, Trit(thirst), Daha(burning sensation), Murcha(fainting), Bhrama(vertigo), Moha(delusion), Hrillus(nausea), Kotha(urticaria), Analsad(suppressed digestion), Romaharsa, Sveda(sweating), Angapitwata(yellow discoloration of the body).This condition is found very rear.[2]Whereas Urdhaga Amlapitta is characterized by vomiting ,where vomiting material is multiple in colored and sour or bitter in taste. It may be associated with sour or bitter belching .Person vomits during digestion of food or in empty stomach. Burning sensation in the throat, chest, and upper abdomen, headache, burning sensation in the palms and sole, loss of appetite, skin rashes, itching and skin problem also found. [3]

Amlapitta include Acid peptic disorders (APD)-gastroesophageal reflux disease (GERD), Peptic ulcer diseases (PUD), dyspepsia and functional disorder of GI tract. APD can affected esophagus, stomach, and duodenum.ADP has varied presentation due to overlapping pathogenic mechanisms which could leads to excessive acid secretion or diminished mucosal defense.[4]Dyspepsia ,a symptom often described as indigestion referring to upper abdominal symptoms usually following intake of food depending upon the Helicobacter pylori infection, obesity, drug-tobacco-alcohol intake, and spicy diet and also lack of sleep.[5]GERD is defined as symptoms or mucosal damage produced by the abnormal reflux of gastric contents into the esophagus or beyond into the oral cavity including larynx or the lungs.[6] Symptoms of GERD are Acid regulation, Heart burn, Epigastric fullness, pressure, pain, Dyspepsia, nausea, bloating, belching, sore throat, dental erosions, asthma etc.[7]PUD is define as disruption in the normal balance of the corrosive effect of gastric juice and the protective effect of mucus on the gastric epithelial cells causes ulceration in the gastrointestinal mucosa. The symptoms includes Epigastric pain, post prandial and nocturnal pain, pain relived with intake of food or antacids. Although absence of pain dose not excludes the ulcer, it may be silent. Other symptoms are nausea, vomiting, and burning sensation in upper abdomen, melena, and perforation, gastric outlet obstruction may also occur.[8] Although currently available pharmacologic approaches can successfully control the aforesaid sign and symptoms but there is still a serious need for novel therapy that will simplify treatment regimens and improve quality of life. In modern medicine, plenty of new drugs are being explored to manage these types of problems but no permanent cure is achieved in most of the cases except symptomatic relief up to some extent. Some time adverse effects of the modern medicine are also seen when administered for longer duration.

In spite of voluminous works done on Amlapitta and its management in Ayurveda, it still remains a common serious problem leading to complications. Therefore, in the present research work, Satavari ghrita was selected to evaluate its efficacy on scientific line to counter or reduce the symptoms of Amlapitta.

2. Materials And Methods

Source of data

Patients of Amlapitta fulfilling the diagnostic criteria were registered from the OPD/IPD of Gopabandhu Ayurveda Mahavidyalaya & Hospital,Puri.

Diagnostic Criteria

Diagnostic criteria were mainly based on the signs and symptoms of Amlapitta described in Ayurvedic classics along with symptomatology of GERD described in modern texts.

Inclusion Criteria

Patient willing for trial was the first and foremost criteria. 20 years to 60 year of age and either sex. Patients were included on the basis of following signs & symptoms-Avipaka(Indigestion),Tikta amla udgara(Bitter and Acidic belching), Hrit kantha daha(Heart burn), Klama(Feeling of tiredness), Utklesha(Nausea), Gourava(Feeling of heaviness), Udara sula(Pain in abdomen), Aruchi(Bloating), Adhmana(Fullness after meal), Vamana(occasional sour and bitter)

Exclusion Criteria

Hematoemesis ,Hyper lipidemia, Peptic ulcer, Duodenal ulcer, Pregnancy & lactation, Pernicious anemia, Diabetes, Patients suffering the disease more than 3 years and other organic diseases.

Investigations

The routine blood tests were advised to exclude the systemic diseases .The investigations were done in every

case before and after the completion of clinical trial such as Heamoglobin gm%, DLC, TLC, ESR, pH of gastric acid, Routine &Microscopic Examination of stool and urine.

Selection and Preparation of Drugs

According to the textual references of Ayurvedic literature and approved synopsis, following drugs were used in the present clinical study to evaluate its efficacy.

For Group-A: Satavari Ghrita **Group-B:** Cow's Ghee

Grouping of patients-Out of 45patients, 40 patients who fulfilled the inclusion criteria were randomly divided into following two groups.

Group A-Total 20 patients in group A were registered and managed with Satavari Ghrita. (Trial Drug)

Group B- In these group 20 patients were registered and managed with Cow's Ghee.(Control Drug)

Duration of trial: The duration of trial was 30 days.

Follow up: Every 15 days period till the completion of therapy. After start of the therapy, the patients were examined in every visit for pulse, blood pressure, temperature, signs and symptoms, appetite, bowel habits and general condition. All the cases were subjected to clinical observation throughout the course of treatment to assess the efficacy of drug from time to time and also to note adverse effect if any. After 30 days, when the trial was completed, thorough examination of the patient was carried out. Whenever felt necessary appropriate investigations were also carried out. The patients who failed to continue the therapy for whole duration were considered drop out cases. After completions of therapy patient were also asked to visit the hospital for untoward effect if any happened.

Dietary Instructions: The patients were asked to avoid spicy foods, particularly red and black peppers, tea, smoking, alcohol, coffee and wine. Counseling was done on every visit to relieve stress and emotional components which may trigger symptoms.

Statistical evaluation and analysis of Result-All the data were collected and then statistically analyzed. The results were made on the basis of grades of various variables compared between pre trial and post trial values in terms of percentage, based on mathematical means and its difference. Values between variables were compared with student (t) paired test for dependent samples by using the degree of freedom p value. Inter group comparison was also done with independent (unpaired) t test. The results were expressed in terms of mean, standard deviation (S.D.) and standard error (S.E.).These

$p <0.0001$-Extremely significant, $p<0.001$ -Highly significant, $p<0.01$-Moderately significant, $p<0.05$ -Significant, $p>0.05$ -Insignificant.

Observations

In this present study, the observation and results have been made on the basis of demographic observations and clinical profile. Total 45 (Forty five) patients were registered. In Group-A, 23 patients and in Group-B, 22 patients were included for clinical trial. 5 patients failed to complete the therapy and were considered dropout. Total 40 patients completed the course of therapy and statistics of those patients are calculated. Under demographic profile, complete study of 40 patients, including distribution of age, sex, education, occupation, dietary habits, appetite and bowel habits, life style etc. has been discussed.

This study shows that the maximum number of patients were in the age group 41-50 years (50%), this was followed with age group 31-40 years(32.5%) and 51-60 years (12.5% each group). 02 patients were in age group 20-30years with 5%age.It is observed that males were more affected with this disease (75%) than females (25%).67.5% of the patients were found married and

32.5% patients were unmarried. It is found that maximum patients 57.5% were graduate. 12.5% patients were primary Pass. 15% patients were high school. 5% patients were post graduate. 10% patients were illiterate.

Patients who suffered from Amlapitta were businessman with percentage of 32.5%. Followed by private job (22.5%). Next 12.5% patients were Gvt.job.5%patients were laborer and 10% patients were farmer only. Maximum patients had mixed food diet with percentage of 75% and only 25 patients were purely vegetarian.

Out of 40 patients 57.5% patients had habit of taking spices and chilies with meals. Only 35% patients were had no habit of eating spices and chilies with meals. And only 7.5%do not taking spices& chilies.

Out of 40 patients 14 patients, (47.5%) had constipated bowel habits. 42.5% had irregular bowel habits and only 10% patients had regular bowel habit. Appetite of 57.5% patients was reduced and 22.5 had increased &20% patients had normal appetite. It is found that 65% patients had not fixed and irregular timing of food intake and 35% patients had fixed and regular timing of food intake.

45% of patients living with sedentary life style and 35% patients living with normal life style. 20% of patients living with hard life style.

Mental status of 47.5% patients was Normal. 27.5% patients were anxious 25% patients had depressed mental status.

Total effect of therapy

After the completion of 30 days of the therapy with Satavari ghrita &Cow's ghee,it is seen that- in group-A, 07 (35%)patients got maximum improvement,09 (45%)patients got moderate improvement, 04(20%) patients have slight improvement in the sign and symptom of the disease. Similarly in group-B, 02(10%) patients

have marked improvement, 07(35%) patients got moderate improvement, 09 (45%) patients got mild improvement, and 02 (10%) patients have no improvement.

Table-1: Showing effect of herapy on different sing and symptoms before and after treatment. (The table shown Under side)

Before Treatment(BT), After Treatment(AT), Standard deviation (S.D.) and Standard error (S.E.), Degree of freedom(DF).

3. Discussion

In this study,40 patients completed the course of therapy who were selected and clinically evaluated. It was found that some factors are very important from the point of view of clinical study. These are Age, Sex, Marital status, Education, Occupation, Dietary habits etc.

1. **Amlapitta in relation to age**- 50% patients were in age group 40-50 years followed by 32.5%patients in 31-40 and 12.5% in 50-60 years. This can be correlated as persons belonging to younger and middle age groups are more prone to Amlapitta due to predominance of pitta dosha in this age group.

2. **Sex-** Out of 40 patients, 75 % patents were male and 25% patients were female only. As males are more exposed to stress and strain, addicted to alcohol and smoking causing mucosal damage and healing to the disease.

3. **Marital Status:** In the present study 67.5% of the patients were married and only 32.5% patients were unmarried, although it is not easy to confirm any concern between marital status and disease. It may because of young middle age group as well as marriages are done in this age group.

4. **Education:** Maximum no of patients 57.5% were educated up to graduate standard. Inadequate sources

of job and income lead to stress and faulty dietary habits leading to vitiation of pitta.

5. **Occupation:** It was observed that maximum patients i.e.32.5% were businessman because they may be under stress due to job insecurity which adversely affects process of digestion, disturbs acid status of stomach and upper gastrointestinal motility.. Higher incidence may be due to mental stress.

6. **Dietary Habits:** Maximum no of patients 75% were on mixed diet. Non vegetarian food is highly spicy and fatty. This has irritant effect on the mucosa of stomach leading to Amlapitta.

7. **Eating spices and chilies in meals:** 57.5% patients had history of taking spices and chilies with meals. This is because spices and chilies have irritant effect on the mucosa of stomach leading to inflammatory response. Moreover, they are Katu Rasa pradhana thus leading to vitiation of Pitta Dosha.

8. **Bowel Habits:** Maximum patients' i.e.47.5% were constipated. Due to mandagni patients were having poor appetite. Small amount of food consumption leads to constipation.

9. **Appetite:** Appetite of 57.5% patients was reduced. This may be due to Mandagni leading to indigestion and loss of appetite.

10. **Timing of food intake:** 65% patients had not fixed and irregular timing of food intake. This may cause improper secretion of HCl leading to incidence of Amlapitta.

11. **Life style:** 45% patients had sedentary life style. Sedentary life style leads to improper digestion of food and thereby to vitiation of Doshas which causes Amlapitta.

12. **Mental Status:** It was observed that mental statuses of 47.5% patients were normal. 27.5% patients were anxious.

13. **Percentage of patients got relief after treatment**: Regarding sign &symptoms in group A all 100% of patients having Hrutkantha daha, Tikta amlaudgara and pH got relief where as 95% having utklesha,65% having vamana,85% having Adhmana got improved. Similarly in group-B 100% of patients having Hrutkanthadaha &pH got relief ,95% having Tikta amlaudgara,80% having utklesha,75% having vamana,95% having Adhmana got improved. It has been observed that after 30 days of treatment 100% improvement regarding pH in both the groups which depicts the action in Amlapitta.

14. **Average percentage change in different sign and symptom**-Improvement in different sign &symptoms in group –A was better than group-B.

15. **Clinical assessment of result**-The final assessment of results of present clinical study was based on estimation of pH, Hritkanthadaha, Tikta amlaudgara, Utklesha, Adhmana, Vamana. The language against improvement was fixed as cured, marked improvement, moderate improvement, mild improvement, and unsatisfactory .After 30 days of treatment it was observed that in group-A, 07 (35%)patients got marked improvement,09 (45%)patients got moderate improvement, 04(20%) patients have slight improvement in the sign & symptom of the disease. Similarly in group-B, 02(10%) patients have marked improvement, 07(35%) patients got moderate improvement, 09 (45%) patients got mild improvement, and 02 (10%) patients have no improvement.

Comparative effect of Satavari ghrita Cow's ghee on different sign &symptoms-

Avipaka- Both the groups show equally highly significant effect.

Hrut kantha daha- although relief of Amlapitta was highly significant in both the groups but comparatively group-A is higher effective than group-B.

Tikta amla udgara-Relief of tikta amla udgara was highly significant in both the groups but comparatively group-A is higher effective than group-B.

Klama-Relief of klama was highly significant in both the groups but group-A is higher effective than group-B

Utklesha-Both the groups show equally highly significant effect.

Gourava-Relief of Gourava was highly significant in both the groups but group-A is higher effective than group-B.

Udarashula –Relief of Udarashula was highly significant in both the groups but group-A is higher effective than group-B.

Aruchi- Relief of Aruchi was highly significant in both the groups but group-A is higher effective than group-B.

Adhmana- Relief of Adhmana was highly significant in both the groups but group-A is higher effective than group-B.

Vamana- Relief of Vamana was highly significant in both the groups but group-A is higher effective than group-B.

pH –The pH level is an important criteria for diagnosis of Amlapitta. This observation reveals that, both the groups were highly effective to increasing pH level in stomach, but comparatively group-A have higher therapeutic effect than group-B.

Probable mode of action of drug: The action of every drug is determined by Rasa, Guna, Veerya, Vipaka and Prabhava.The fundamentals regarding treatment in Ayurveda are mainly based on the Dosha Chikitsa. In Amlapitta the main Dosha is Pitta (Pachaka Pitta). Digestion process is under the control of Pachaka Pitta, Samana Vayu and Kledaka Kapha. The Dushya in the disease is Rasa. The inefficient action of Pitta and Agni lead to Agnimandya, due to Agnimandya, Aama is

produced which vitiates Rasa. The vitiated Rasa leads to further Agnimandya and Avipaka.That's why the drug was selected for study had mainly Pitta shamaka, and vata shamaka properties along with Deepana, Pachana, Rochana, Anulomana action.

These drugs are having the following properties.

Sr. No.	Drug	Rasa	Veerya	Vipaka	Doshaghnata
1	Satavari	Madhura, Tikta	Sheeta	Madhura	Vatapitta shamaka
2	Go dugdha	Madhura	Sheeta	Madhura	Vatapiita Shamaka
3	Ghrita	Madhura	Ushna	Madhura	Pittavatta Shamaka

On the basis of Rasa

a. All the three ingredients are having *Madhura Rasa* which is *Pittashamaka* thereby acting on *Amlapitta* .

b. *Madhura Rasa* is having *Sheeta, Snigdha* and *Guru* Properties. These will counter the *Ushna, Tikshna* and *Laghu gunas* of *Pitta Dosha. Madhura Rasa* is *Pitta vata shamaka*.

c. *Tikta Rasa* has *Ruksha, Sheeta* and *Laghu* properties, due to these properties these *Rasas* will remove *srotorodha, Aama pachana* and *vata anulomna* as well as both Rasa are *Pittakapha shamaka. Tikta rasa* is also having properties like *Deepana, Pachana, Rochana* which are opposite to symptoms of *Amlapitta*.

On the basis of *Veerya*: So far *Veerya* is concerned; the analysis of all contents of *Satavarighrita* would reveal that out of three ingredients two are having *Sheeta veerya* which is *Pitta shamaka*.

On the basis of *Vipaka*: Regarding *Vipaka*, all the ingredients are *Madhura Vipaka* in nature. The *Madhura vipaka* is said to be *Pitta Shamaka*. The *Madhura Vipaka* has got a soothing effect on the body tissues and helps in the production of fresh and healthy tissues. On the basis of

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this logical reasoning it may be said that in different inflammatory conditions where tissues are degenerated or undergone ulceration are regenerated by the *Madhura Vipaka*. As well as *Madhura Vipaka* is having *Srishta Vinmootra* property this will lead to Vatanulomana.

On the basis of Doshaghanta: All the three drugs have *Vata Pitta Shamaka* action.Thus the drug which was used in the clinical trial not only pacifies vitiated alleviates *Pitta Dosha* but also have *Vatahara* action,which enable it to counteract the disease process especially manifestation of vitiated *Pitta.*

4. Conclusion

After 30 days of therapy Group-A and Group-B were equally effective over symptoms like *Vamana, Utklesha, Adhmana. Tiktamlodgara, Hrutkantha daha & pH* was improved to a greater extent in group A than group-B. From this study it is revealed that though both drugs are significantly effective in the treatment of Amlapitta , trial drug is highly effective in comparison to control drug. The effect of Satavari ghrita is highly significant in case of patients of chronic condition as compared to acute condition of the disease. Patients should keep his/her eating habits under control and avoid food & habits which are adverse for his ailment. Well cooked fresh meals taken at short- intervals four to six times a day are useful. Low fiber diet is good for patients of *Amlapitta*. Seasoned rice, *moong* like pulses, cow's milk and cow's ghee are described as good for patients. The importance of fluid, bland and non-irritating diet has been well recognized in *Ayurveda* for *Amlapitta*.

The prevalence of disease has been bound to increase with changing life styles, irregular food habits, physical and mental stress. The management skills will of course largely depend on correction of lifestyle. The importance of *Dincharaya, Ritucharya and Ahara-Vihara* cannot be over stressed in such circumstances. However, underlying pathogenesis needs to be better understood for successful management, even for symptomatic relief.

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Table-1: Showing effect of herapy on different sing and symptoms before and after treatment.

Sign &Symptom			Mean±SD	Mean diff±S.E	D.F	t Value
AVIPAKA	SG	BT	1.38±0.60	1.27±0.108	17	11.82
		AT	0.11±0.32			
	CG	BT	1.5±0.70	0.61±0.11	17	5.54
		AT	0.88±0.67			
HRUTKANTHA DAHA	SG	BT	2.5±0.60	2±0.125	19	16
		AT	0.55±0.51			
	CG	BT	2.3±0.57	0.45±0.11	19	4.09
		AT	1.8±0.52			
TIKTA AMLA UDGARA	SG	BT	2.5±0.51	2.05±0.114	19	17.98
		AT	0.45±0.51			
	CG	BT	2.42±0.60	0.52±0.11	18	4.72
		AT	1.89±0.45			
KLAMA	SG	BT	1.12±0.34	1±0.09	15	11.11
		AT	0.125±0.341			
	CG	BT	1.16±0.38	0.27±0.1	17	2.7
		AT	0.88±0.58			
UTKLESHA	SG	BT	1.94±0.52	1.21±0.094	18	12.87
		AT	0.73±0.45			
	CG	BT	1.57±0.60	0.52±0.11	18	4.72
		AT	1.05±0.70			
GOURAVA	SG	BT	1.41±0.61	1.17±0.126	16	9.33
		AT	0.29±0.46			
	CG	BT	1.47±0.62	0.58±0.12	16	4.83
		AT	0.88±0.78			
UDARASULA	SG	BT	1.47±0.62	1.41±0.148	16	9.53

		AT	0.05±0.24			
	CG	BT	1.66±0.68	0.61±0.11	17	5.54
		AT	1.05±0.72			
ARUCHI	SG	BT	2.3±0.73	1.6±0.196	19	8.16
		AT	0.7±0.47			
	CG	BT	1.84±0.76	1.21±0.09	18	13.44
		AT	0.63±0.68			
ADHMANA	SG	BT	2.52±0.51	1.88±0.145	16	12.97
		AT	0.64±0.60			
	CG	BT	1.85±0.81	0.65±0.10	19	6.8
		AT	1.2±0.61			
VAMANA	SG	BT	1.53±0.66	1.38±0.18	12	7.66
		AT	0.15±0.37			
	CG	BT	1.6±0.73	0.6±0.12	14	5
		AT	1.0±0.65			
pH	SG	BT	1.58±0.43	2.59±0.16	19	16.18
		AT	4.17±0.93			
	CG	BT	1.7±0.47	1.47±0.17	19	8.64
		AT	3.18±0.80			