

CLINICAL EFFECTIVENESS OF SIDDHAMRITA RASA IN AMLAPITTAM-A COMPARATIVE STUDY

¹Gupta Shilpi

¹Assistant professor, département of rasashastra & bhaishjya kalpana, Mahatma jyotiba phule Ayurvedic Medical college and Hospital, Jaipur(Rajasthan)

ABSTRACT:

Amlapittam is a gastrointestinal disorder frequently encountered in day to day practice. *Amlapittam* may be fatal if it is not diagnosed properly and lead to development of other serious gastro-intestinal disorders. Due to pain, discomfort and other symptoms work absenteeism; social Phobia's and other negative quality of life effects can be common. Considering the unpleasant effects of this disease, this study was undertaken. The clinical study was conducted as an active concurrent randomised clinical trial in two groups A and B containing 20 patients in each group. *Laghu sutashekhara rasa* was used as a control. The fine powder (*churna*) of *Sphatika* and *Gairika* was subjected to *mardana* (grinding)) in the *khalwa* (mortar) .The dose of trial drug and control drug given was 1gm in the morning before meals. For both the groups, symptomatic evaluation of the patients was done before treatment and for every 15days after the completion of intervention of drug. From the Clinical study, it was concluded that the drug combination showed highly significant reduction ($p<0.001$) in alleviating Pain, *Amlodgara*, *Avipaka*, *Shula* and *Chardi*. Thus, the study revealed that the *Siddhamrita Rasa* has significant effect in management of *Amlapittam*.

Keywords: *Amlapittam, Siddhamrita Rasa, Randomised clinical trial*

INTRODUCTION: *Amlapittam*¹ (Hyperacidity) terminology is relatively a new concern in *Ayurvedic* classics. *Amlapittam* is the most common disorder of the present society. The word *Amlapittam* indicates *amlattavam* of *pitta* because the *pitta* instead of attaining its natural *katupaka* attains *amlapaka* .One of the most prevalent theories currently being evaluated is the possible involvement of *H.pylori* infection in Dyspepsia (mainly in ulcers). *Siddhamrita rasa*² contains *Sphatika* (Potash Alum) and *Suvarna Gairikam*(Fe_2O_3). *Gairika* and *Sphatika* in such a combination as in *Siddhamrita rasa* becomes potent enough to use it in *Amlapittam* which requires immediate effect. *Laghu soota shekhar rasa*³ is control drug. Previous studies have proved its efficacy on *Amlapittam*. Hence, an

attempt has been made to evaluate effectiveness of *Siddhamrita Rasa* over to *Laghu Soota Shekhar Rasa* in the management of *Amlapittam*.

MATERIALS&METHODS

objectives of the study:Evaluate the effectiveness of *Siddhamrita rasa* against *Laghu soota shekhar rasa* on *Amlapittam*.

hypothesis: Null hypothesis-There is no significant difference between the effect of *Siddhamrita rasa* and *Laghu soota shekhar rasa* in *Amlapittam*. Alternative hypothesis-There is significant difference between the effect of *Siddhamrita rasa* and *Laghu soota shekhar rasa* in *Amlapittam*.

pharmaceutical study: Preparation of *Siddhamrita Rasa*

Reference: *Rasa yoga sagar* Part 2, Yoga no.390

Materials:

1- *Sphatika* (alum) is taken after the *shodhana* (purification) with *Dhnyamla* (Sour gruel) – 300gms

2- *Gairika* is taken after the purification *shodhana* (purification) with *Godugdha* (cow's milk purified – 100 gms
Method: *Mardana* (Trituration)

Procedure: *Shuddha Sphatika* was taken in a mortar and made into fine powder. Then fine powder of *Shuddha Gairika* was added and mixed. Both the ingredients are mixed together to form a homogenous mixture. The *mardana* (trituration) process was done until very fine powder was obtained. Well prepared powder was divided in 1gm dose of each. Each 1 gm of powder was kept in seal lock packet. Colour of the powder became reddish orange after mixing *sphatika* and *gairika* together.

clinical study

research design: Active concurrent Parallel Randomised control trial. Single Blind

study drug: *Siddhamrita rasa*²

Route of drug administration:

The fine powder of *Siddhamrita Rasa* was made and administered internally (orally). *Laghu Sootashekhara Rasa* powder was also made and used internally (orally) as a control drug.

Inclusion criteria:

Age group- 16 to 60 years.

Patients were selected irrespective of sex, caste, profession etc.

- Patients who were willing to participate in the study.
- Patients with classical sign and symptoms of *Amlapittam* as per classical reference like *Amlodgar*, *Daha*, *Udarshoola*, *Chardi*, *Avipaka* etc. *Agni* and associated symptoms

Assessment criteria :

1. *Daha* (burning sensation):

- No *Daha* - 0
- *Daha* of mild degree in any area of *Kantha* (throat), *Udar*(stomach), *Ura* (heart), *Kukshi* (abdomen)- 1
- *Daha* of moderate degree relieves by milk, cold drink, antacid - 2
- *Daha* of severe degree involving *Hrita*, *Kantha* etc. and relieved after digestion of feed, vomiting -3
- Severe degree of *Daha* involving major Areas of abdomen but does relieve by any measures mentioned above - 4
- Severe degree of *Daha* involving the whole body like hands, feet and pts. Feels like entering the fire and does not get relief by any measure - 5

2. *Amlodgara* (regurgitation):

- No *Amlodgara* at all - 0
- Sometimes during day - 1
- *Amlodgara* moderate severity - 2
- Severe *Amlodgara* disturbing the patients – 3
- Small amount of fluid regurgitate to patients mouth – 4

3. *Chardi* (nausea-vomiting):

- No vomiting at all - 0
- Feels sense of nauseating and vomits occasionally - 1
- Frequency is not more than 2 to 3 per week - 2
- Frequency of vomiting is between 4 to 6 per week and comes whenever *Daha* or pain is aggravated - 3
- Frequency of vomiting is daily - 4
- Frequency of vomiting after every meal - 5

4. *Shula* (pain):

- No pain - 0
- Slight pain which need not any medicine - 1

- Pain of some degree which subsides after taking some Cold, Sweet, Food, Alkali, Antacids, Milk etc. - **2**
 - Severe colicky, piercing or boring unbearable pain but relieves after vomiting or relieves after digestion of food - **3**
 - Severe unbearable pain which does not subside by either vomiting or antacids, the patients awakes in the night due to pain - **4**
 - Unbearable severe pain which does not subside by any measure, associated frequent vomiting and hematemesis - **5**
- 5. Avipaka (indigestion):**
- No Avipaka - **0**
 - Avipaka occurs occasionally 2 – 3 times per week - **1**
 - Avipaka occurs daily but not severe - **2**
 - More than 2–3 Ajeerna Ahara Lakshan's like AshuddhaUdgara (burping)/ Anutsaha (laziness)/ Amalamutrapravrutti (acidic urination)/ Guruta (heaviness) / Glani (lassitude) / Marutmudata (horripilation) present - **3**
 - Avipaka is of severe type which does not subside without medicine & Langhana and which disturbs the routine of patient - **4**

Assessment of the cases was done based on appropriate scores to sign and symptoms.

All signs and symptoms were assigned scores, depending on their severity to assess the effect of drug, on 0th, 21st, 36th, 51st day respectively.

Total assessment of the therapies was done on the basis of relief in the main signs and symptoms of disease, Agnidushti and general signs and symptoms of disease.

Effect on Agni and associated symptoms:

- 1) All the symptoms were given '2' scores to each if found present at all.
- 2) If any improvement in the symptom was noticed then it was given '1' score.
- 3) If the symptom was found absent then it was given '0' score.
- 4) If no improvement was reported then the score assigned was '2'.

This assessment was done before and after the treatment in both the groups. The score thus obtained before and after the treatment was statistically analysed.

Exclusion criteria:

Patients who had chronicity for more than three years.

Known cases of Gastric Ulcer, Duodenal Ulcer, CA Stomach, Hematemesis, Melena, having major illness like cardiac disease, diabetes, and any other systemic diseases were excluded from the trial.

Patients who were taking NSAIDS, STEROIDS for long time.

Pregnant and lactating mother.

sampling: Patients were divided into **two** groups.

Group A: Trial drug

Group B: control drug

sample size: 20 in each group.

sampling technique: Randomised selection of patients was done by lottery method.

Intervention schedule:

Particulars	Trial group (A)	Control group(B)
Sample size	20	20
Drug	Siddhamrita rasa	Laghu soota shekhar rasa
Form	Powder form	Powder form
Anupana	Goksheera	Sita yukta Goksheera
Diet	Standard*	Standard*
Duration	21 days	21 days
Dose	1masha(1gm)powder form in the morning	1gm in the morning

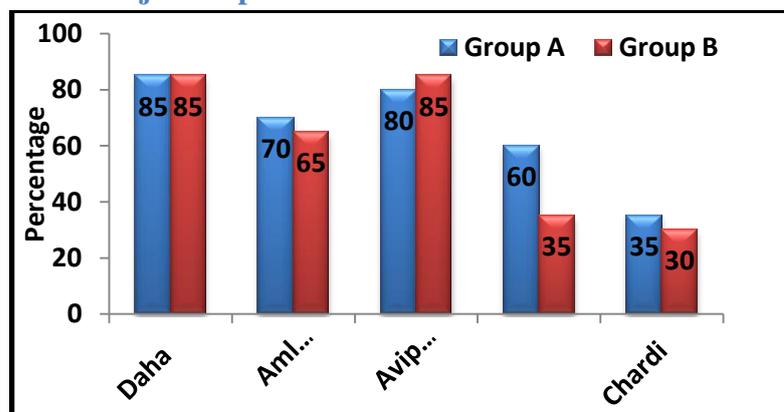
*Standard diet: Patient was advised not to take too much oily and spicy food.

parameters of the study (outcome variables): Daha, Amlodgara, Shoola, Avipaka, Chardi, Agni and associated symptoms^{4,5,6}. All signs and symptoms were assigned scores, depending on their

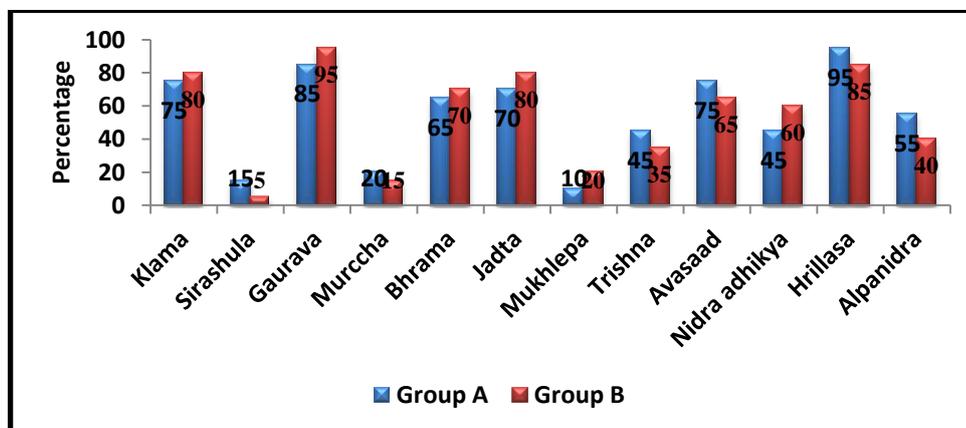
severity to assess the effect of drug, on 0th, 21st, 36th, 51st day respectively. Total assessment of the therapies was done on the basis of relief in the main signs and symptoms of disease, Agnidushti and general signs and symptoms of disease.

OBSERVATION AND RESULTS:

subjective parameters wise distribution:



associated features wise distribution:



DISCUSSION:

discussion on pharmaceutical study:

Two methods have been told for *Shodhana* of *Sphatika*; i.e. Dipping in *Dhanyamla* and De-watering. Here in this study both methods were adopted as per *Rasa mitra*⁷. It was also useful in view of preparation and to enhance the shelf life of the drug. The media i.e. *Dhanyamla* used in *Shodhana* has attributed some more quality to *Sphatika*. It minimized its toxic effect, decreases its particle size due to its *Tikshna*, *Laghu* properties. *Dhanyamla* has *Bhedaka*, *Pachaka*, *Shulaghna*, *Vastishodhaka* properties which were adapted by *Sphatika* in *Shodhana* process. *Utfullikarana* (de-watering) was done to remove water of crystallisation and to make *Sphatika* brittle and light weighted. *Shodhana* of *Gairika*^{8,9} was done by bhavana in godugdha (cow's milk) in the present study. when *Gairika* is levigated with cow's milk ferrous ion converted into ferric form. Fe^{+3} are absorbed easily and carried in the plasma by protein transferring. Cow's milk used for levigation is having *Madhur rasa*, *Sheeta virya*, *Mrudu* and *Guru* in *guna*. These properties of cow's milk may be acquired by *gairika* during trituration process. So, *Shodhana* process may increases the absorption rate of *Gairika* in body.

discussion on preparation method of siddhamrita rasa

The *Mardana* process was done until very fine mixture was obtained. The mixture was of neutral type which was static in the behaviour. The process used in the

preparation of the drug is Diffusion mixing¹⁰; i.e. random motion of the particles. It is produced by any form of agitation of powder.

discussion on clinical study trial:

Active con-current randomised control trial was selected to comprehend the evidence base effect of trial drug over a well-established drug.

discussion on data relating to socio-demographic background

Age: This age pattern is suggestive of the higher prevalence of *Amlapittam* in middle aged group which is *Pitta* predominant period of life.

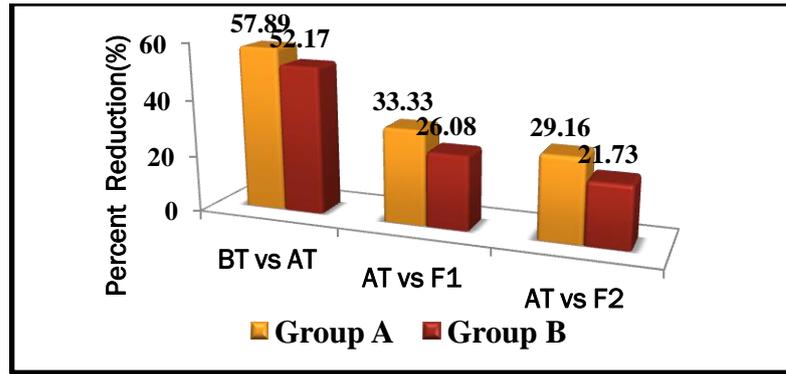
Gender: The reporting of more number of females may be due to their stressful conditions.

Socio-economic Status: Middle classes people are generally consuming the more Masala diet with provoke the *Pitta-kapha* dosha predominantly.

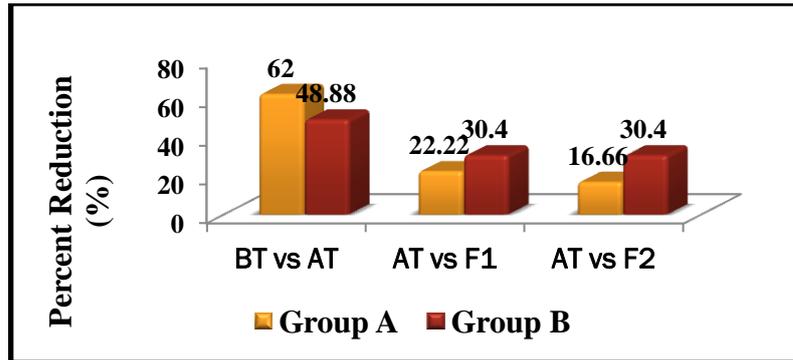
Manas Bhavasa: (35% and 45%) were having *Chinta*, 30% had *Shoka* and 30% had *Krodha*. For the process of digestion your *Manasika Bhavas* should be under control. All these symptoms lead to *Rasa dhatukshaya*.

Addiction and beverages: All patients were taking either tea or coffee. 50% patients were using smoking and 15% were taking alcohol. These factors are mostly irritant to gastric mucosa and thus cause *daurbalya* of *Amashaya* along with vitiation of *Dosha* mainly *Pitta-kapha*.

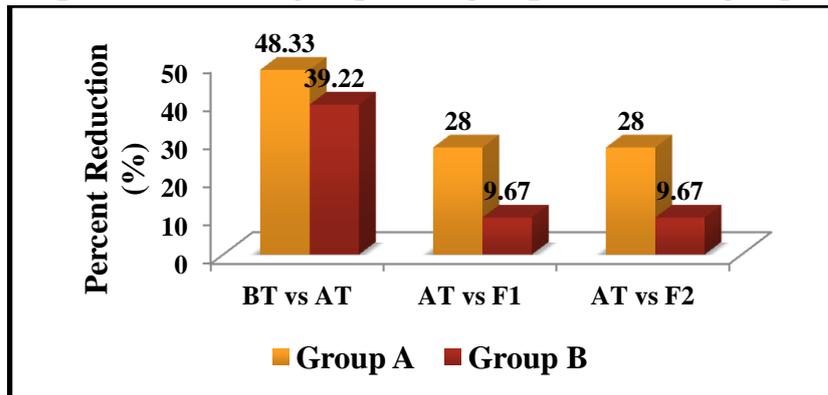
Comparison between group a and group b in reducing daha:



comparison between group a and group b in reducing *amlodgara*:



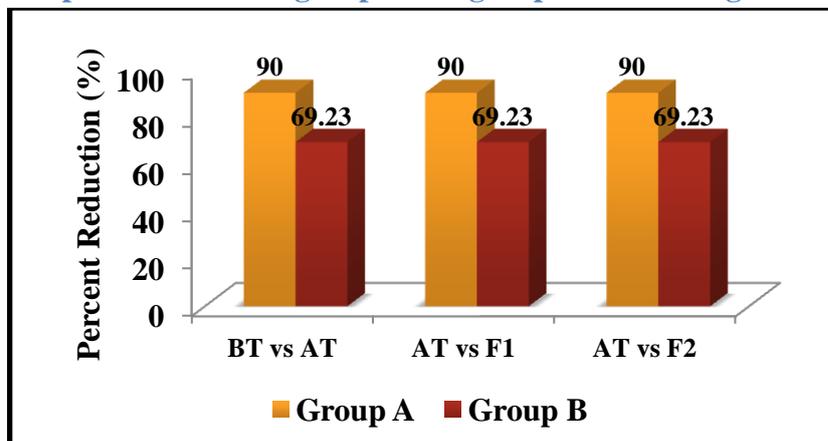
Comparison between group a and group b in reducing *avipaka*:



it can be concluded that the study drug had marked relief in reduction in Shula at the early stage but not possess carry over

effect, While control drug has more surplus effect after the intervention also.

comparison between group a and group b in reducing *chardi*:



The effect was remained the same throughout the follow-ups.

discussion on mode of action of the

drug: *Siddhamrita rasa* contains *sphatika* and *gairika* in it. Antacid activity of the drug may be attributed by the pharmacological properties of both the drugs. *Daha* (Burning sensation) is suppressed by *kashayas*(astringent) and *madhur* (sweet)*rasa* and *sheeta virya* (cold potency) properties of the drug. *Amlodgara* (regurgitation) is diminished by *madhur* and *kashaya rasa* and *madhur vipaka* of the drug. The main cause of *Avipaka* (Indigestion) is *Agnimandya* which is corrected by *katu* (pungent) and *amla rasa* of the drug. Also *Gairika* and *Sphatika* both are called *vishaghna* (antipoisonous) which is active property in combating to formed *annavisha* (undigested food) due to *Mandagni*. *Shula* (pain) in *Amlapittam* is triggered due to vitiated *vata* dosha along with *pitta* which is corrected by *snigdha guna* (unctuous), *sheeta virya* and *kashaya rasa*. *Chardi* (nausea and vomiting) and *Daha* (Burning sensation) in *amlapittam* are seen when *parana vayu* combines with *pitta*; it may be rectified by *snigdha guna* and *madhur vipaka*. *Udan vayu* with vitiated *pitta* causes *murcha*, *bhrama*, *daha* and *klama* which are also conquest by *snigdha guna* and *madhur vipaka*. In a nut shell *Siddhamrita Rasa* is acting in treatment of *Amlapittam* by the virtue of its *snigdha guna*, *madhur vipaka* and *madhur rasa* which is having the properties of digestive, astringing and anti-inflammatory in nature. According to the modern pharmacological action of the drug, this contains alum in major quantity as an ingredient which is highly astringent in action due to which it delays the absorption of toxins from gastric mucosa. Aluminium sulphate¹¹ is hydrolyses to form the aluminium

hydroxide precipitate and a dilute sulphuric acid solution accordingly it acts like an acidic buffer. *Gairika* is a stringent and cooling in property so it might be useful for mucosal membrane of Gastro-intestinal tract.

anupana: *Godugdha*¹² (cow's milk) was selected as *anupana* for *Siddhamrita rasa* which varies with control drug. The reason behind this; *anupana* for the drug is indicated by acharya in the reference and to determine the exact mode of action of the drug it was important to follow the directions. *Godugdha* (cow's milk) used for *anupana* is having *Madhur rasa*(sweet), *Sheeta virya*(cold potency), *Mrudu*(soft) and *Guru*(heavy) in *guna*. It is also having *Amlapittahara*¹³ (antacid) property specified by Acharyas in classics. Drug intake timing: Medicine was advised to give at the time of *Pragbhatkala*¹⁴ which is the first time for intervention by Acharyas. It is advised for *pitta prakopa* stage.

CONCLUSION: From this study it can be concluded that non-compliance of code of healthy diet selection and eating plays a major role in causation of this disease. Hence we can say that code and conduct of healthy eating is important to achieve early and better result of the treatment as *Nidana Parivarjana* (avoidance of causative factors). The irresistible stress and strain of this Study drug showed prompt result in dropping the symptoms like *daha*, *amlodgara*, *shula*, and *chardi* while Control drug has the sustained effect on these symptoms. so it can be concluded from the study that both the drug had almost same effect on the symptoms but for quick relief on these symptoms study drug might be useful in such conditions. It is a cost effective drug which is also easy to

prepare.present era In a nut shell *Siddhamrita Rasa* is acting in treatment of *Amlapittam* by the virtue of its *snigdha guna, madhur vipaka* and *madhur rasa* which is having the properties of digestive, astringing(checking the secretions) and anti-inflammatory in nature.

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Corresponding Author: Dr.Shilpi Gupta
Assistant professor, département of rasashastra & bhaishjya kalpana, Mahatma jyotiba phule Ayurvedic Medical college and Hospital, Jaipur(Rajasthan)
Email : drguptashilpi@yahoo.com

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