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 gastrointestinal 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 sutashekhar 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 15 days 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 (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 contains Sphatika (Potash Alum) and Suvarna Gairikam(Fe₃O₄). 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 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 Shekher 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 *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

**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

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 subsides 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:**

<table>
<thead>
<tr>
<th>Particulars</th>
<th>Trial group (A)</th>
<th>Control group (B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Drug</td>
<td>Siddhamrita rasa</td>
<td>Laghu soota shekhar rasa</td>
</tr>
<tr>
<td>Form</td>
<td>Powder form</td>
<td>Powder form</td>
</tr>
<tr>
<td>Anupana</td>
<td>Goksheera</td>
<td>Sita yukt Goksheera</td>
</tr>
<tr>
<td>Diet</td>
<td>Standard*</td>
<td>Standard*</td>
</tr>
<tr>
<td>Duration</td>
<td>21 days</td>
<td>21 days</td>
</tr>
<tr>
<td>Dose</td>
<td>1masha(1gm) powder form in the morning</td>
<td>1gm in the morning</td>
</tr>
</tbody>
</table>

*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. 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:**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daha</td>
<td>85</td>
<td>85</td>
</tr>
<tr>
<td>Amlodgara</td>
<td>65</td>
<td>70</td>
</tr>
<tr>
<td>Shoola</td>
<td>85</td>
<td>80</td>
</tr>
<tr>
<td>Avipaka</td>
<td>60</td>
<td>35</td>
</tr>
<tr>
<td>Chardi</td>
<td>35</td>
<td>30</td>
</tr>
</tbody>
</table>

**Associated features wise distribution:**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Klama</td>
<td>75</td>
<td>85</td>
</tr>
<tr>
<td>Strashula</td>
<td>85</td>
<td>85</td>
</tr>
<tr>
<td>Gaurava</td>
<td>85</td>
<td>85</td>
</tr>
<tr>
<td>Murchha</td>
<td>65</td>
<td>70</td>
</tr>
<tr>
<td>Bhrama</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>Jastta</td>
<td>35</td>
<td>45</td>
</tr>
<tr>
<td>Mukkhepa</td>
<td>75</td>
<td>65</td>
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<td>Trishna</td>
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<tr>
<td>Ausaad</td>
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</tr>
<tr>
<td>Nidra adhiya</td>
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<td>85</td>
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<tr>
<td>Harisasa</td>
<td>55</td>
<td>40</td>
</tr>
<tr>
<td>Alpanidara</td>
<td>75</td>
<td>35</td>
</tr>
</tbody>
</table>

**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. 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 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 inguna. 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 mixing; 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 sulphate 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 (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 acharyas 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 (antacid) property specified by Acharyas in classics.

Drug intake timing: Medicine was advised to give at the time of Pragbhatkala 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.

REFERENCE:
2. Vaidya pandit Hari prapanna Sharma, Rasa yoga sagar part 2, Banaras, Krishna das academy published 1983, yoga no 390, verses no 1753, 1754, 1755
3. Krishna Gopala; Rasathanthrasara nama sidhaprayogasamgraha; Ajmer; A V Bhavan, 1956; kharleeya rasayana page no 330
5. Prof. P. V. Tiwari, Kasyapa Samhita, Reprint Edition 2013, Varanasi, Chaukhambha Bharti Academy. Khil Sthanam Chapter 16/19; Page No. 631
13. Vaidya Yadavaji Trikamji, Editor, Charaka Samhitha Of Agnivesha With Ayurveda Dipika Commentary By Chakrapaniji; Varanasi, Choukhambha Sanskrit Prasthan, Sootra Sthan, 1984, Chap 25, Ver 40, Page No: 131

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