A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF GUDADI MODAKA AND DRAKSHADI GUTIKA IN AMLAPITTA

Archana A. V¹, Susheet Shetty²

¹Final year PG Scholar, Dept of Kayachikitsa, Alva’s Ayurveda Medical College, Moodbidri, India
²Guide, Dept of Kayachikitsa, Alva’s Ayurveda Medical College, Moodbidri, Karnataka, India

Email: archanaayumahe@gmail.com

ABSTRACT

Background and Objectives: Amlapitta is disease having direct link with type of food consumed, food habit, food timing, lifestyle, timing of work, rest and type of work. Madhavakara has described that already Sanchita pitta when become Vidagdha due to pittaprapakopaka nidana leads to Amlapitta with the symptoms Amla-Tikta Udgar, Hrit-Kanta Daha, Avipaka, Klama, Uklesha, Gourava, and Aruchi. Gudadi Modaka and Drakshadi Gutika are two formulations which possess the properties like tikta-madhura rasa, madhura vipaka, sheetha virya, with pittakaphahara and Agnikara karma will help in the management of Amlapitta. Methods: It was a single blind randomized comparative clinical trial. The study was conducted in 40 subjects for a period of 30 days. Observations were analyzed and findings were evaluated by using statistical methods. Results: The severity of Symptoms markedly reduced in both the groups which is statistically significant and On comparing the effect of Gudadi Modaka and Drakshadi Gutika, there was no statistical difference obtained. Conclusion: The result suggests that both Drakshadi Gutika and Gudadi Modaka have significant effect in Amlapitta. There is no significant difference in the effect of Drakshadi Gutika and Gudadi Modaka in Amlapitta.

Keywords: Drakshadi Gutika, Gudadi Modaka, Amlapitta

INTRODUCTION

In this rapidly growing civilization and multimedia technology life become full with stress having more speed and accuracy are the prime demands. So, people neglect healthy foods and are attracted towards the junk food causing many psychological disorders which hampers the digestion. Non-ulcer dyspepsia refers to a state of Stomach, where Gastric acid levels are higher than the reference range and it produces symptoms like Heartburn, Nausea, vomiting of sour liquid, Belching, Flatulence.¹ This pathological disorder covered under the broad umbrella of Amlapitta in Ayurveda and the Signs and Symptoms of Amlapitta mentioned in the Ayurvedic texts are similar to non-ulcer dyspepsia. Charaka samhitha clearly indicates that Amlapitta occurs in the person who does not check the temptation of food.² Acharya sushruta mentioned prakrita rasa of pitta as katu and vikrita(Vidagdha) rasa of pitta as amla and increased vidagdha will results in excessive production of amla guna of pitta leading to the condition Amlapitta.³ Madhavakara has described that already sanchita pitta when become vidagdha due to pitta prakopaka nidanas leads to Amlapitta and produce the symptoms like Amla-Tikta.
Udgara, Hrit-Kanta Daha, Avipaka, Klama, Utklesha, Gourava, and Aruchi.  

Gudadi Modaka and Drakshadi Gutika are two formulations which possess the properties like tikta-madhura rasa, madhura vipaka, sheetha virya, laghu guna with deepana-pachana, pitta-kaphahara and agnivardaka karma will help in the management of Amlapitta. Gudadi Modaka and Drakshadi Gutika are mentioned and specially indicated in Amlapitta and the formulation Gudadi Modaka contains pippali, haritaki, guda and Drakshadi Gutika contains draksha, haritaki and sita. These formulations also have properties like pitta-shamaka, deepana–pachana and agnivardaka since Amlapitta is a pitta predominant condition.

AIM AND OBJECTIVES
1. To evaluate therapeutic effect of Gudadi Modaka in Amlapitta.
2. To evaluate therapeutic effect of Drakshadi Gutika in Amlapitta.
3. To compare the therapeutic effect of Gudadi Modaka and Drakshadi Gutika in Amlapitta.
4. To make a comprehensive literary review on Amlapitta.

MATERIALS AND METHODS

SOURCE OF DATA
1. Literary Source: All Ayurvedic, Medical literatures, Contemporary texts including journals and websites about the disease and medicine were reviewed and documented for the planned study.
2. Drug source: Raw drugs required were identified and collected from the source of availability and the medicines prepared according to the classical references at Alva’s Pharmacy, Mijar.
3. Sample source: Patients diagnosed as Amlapitta were randomly selected from O.P.D and I.P.D of Alva’s Ayurveda Medical College and Hospital, Moodbidri, Medical camps and other referrals.

ETHICAL CLEARANCE – ICEC/KC/O1

METHOD OF SAMPLING
Simple Random Sampling Method

CRITERIA FOR SELECTION OF PATIENTS

Diagnostic Criteria
Diagnosis were done based upon the presence of 4 main samanya lakshanas viz Tikta-udgara, Amla-udgara, Hridaya, Kantada with or without the presence of other lakshanas of Amlapitta.

1. Tikta-udgara
2. Amla-udgara
3. Hridaya
4. Kantada
5. Utklesha
6. Avipaka
7. Gourava
8. Aruchi
9. Klama

Inclusion Criteria
1. Patients between the age group of 16-60 years.
2. Patients diagnosed with Amlapitta.
3. Patients fulfilling the Diagnostic Criteria.
4. Chronicity not more than 3 months.

Exclusion Criteria
1. Patients who do not give written consent for clinical trials.
2. Patient diagnosed with Malignancies.
3. Patients with history of Hematemesis, Melena.
4. Patients with Drug Induced Amlapitta.
5. Lactating and Pregnant women.

METHOD OF MEDICINE PREPARATIONS

GUDADI MODAKA

<table>
<thead>
<tr>
<th>TABLE 1: INGREDIENTS OF GUDADI MODAKA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pippali</td>
</tr>
<tr>
<td>Haritaki</td>
</tr>
<tr>
<td>Guda</td>
</tr>
</tbody>
</table>

Dried pippali and haritaki was collected and all made into fine powders. Equal part of haritaki, pippali and guda were taken. Firstly, guda paka was prepared and then Haritaki and Pippali churna were mixed thoroughly and sieved to get fine Powders then thick Jaggery solution (after obtaining (Tantupaka) is made to which the sieved powder is added and mixed. The drug obtained semisolid paste consistency. 2gm of Vati were prepared immediately before the semisolid paste loses its warmthness and packed in plastic
containers which are then sealed using machine. Vati were prepared instead of Modaka because of Practical difficulty and also for patient’s convenience. Plz correct it grammatically

**DRAKSHADI GUTIKA**

**TABLE 2: INGREDIENTS OF DRAKSHADI GUTIKA**

<table>
<thead>
<tr>
<th>INGREDIENT</th>
<th>QUANTITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRAKSHA</td>
<td>VITIS VINIFERA</td>
</tr>
<tr>
<td>HARITAKI</td>
<td>TERMINALIA CHEBULA</td>
</tr>
<tr>
<td>SITA</td>
<td>SUGAR CANDY</td>
</tr>
</tbody>
</table>

In the above mentioned drug one part of haritaki, one part draksha and two parts of sita were taken and made it into fine powders, at the same time the draksha was grinded well and the paste was prepared. Haritaki powder was mixed to the paste of draksha in mortal and pestle and triturated well to attain a homogenous mixture, then to this mixture two parts of Sita was added and Gutika of 2 gm each were prepared by weighing with the help of electronic weighing machine. Thus formed gutika was kept for two days and packed in air tight bottles.

**STUDY DESIGN**

Single Blind Randomized Comparative Clinical Study

**INTERVENTION**

The intervention of clinical study was carried according to individual groups mentioned below. These groups assigned as A and B were treated with Gudadi Modaka and Drakshadi Gutika respectively.

- **Group A**: Gudadi Modaka 6gm orally twice daily before food with Ushnodaka for a period of 30 days.
- **Group B**: Drakshadi Gutika 8gm orally thrice daily before food with Ushnodaka for a period of 30 days.

**Observational Period**: Patients were observed before treatment and after 15th, 30th and 45th day of study period. The assessment of the condition was done based on the detailed Proforma adopting standard scoring methods of Subjective parameters. Both group were compare by using following Statistical Analysis:

**DISCUSSION ON OBSERVATION**

**Age**: In the sample of 40 patients of Amlapitta, it was observed that maximum number of patient were from the age group of 26-35 years (42.5%). This is the age of Pitta predominance which may be the reason for high incidence in the particular age group.

**Ahara Vidhi**: It was observed that 52.5% patients followed Vishamashana, which shows the contribution of Vishamashana for the manifestation of disease Amlapitta.

**Aggravating Period**: The aggravation of symptoms was observed more in afternoon (47.5%) and evening (22.5%) due to Pittaprakopa kala.

**Mental Stress and Strain**: 72.5% patients had mental stress and strain which shows the influence of Manasika nidana over the manifestation of disease.

**RESULTS**

The study was carried out in patients of Amlapitta in 2 groups of which Group A received Gudadi Modaka and Group B received Drakshadi Gutika for a period of 30 days. Data was collected before the Treatment, after 15th, after 30th and after 45th day of study period. The assessment of the condition was done based on the detailed Proforma adopting standard scoring methods of Subjective parameters. Both group were compare by using following Statistical Analysis:
Non Parametric test average was found using Arithmetic mean and Percentage
Pre-Post Comparison done by Paired ‘t’ test.

Student ‘t’ test is applied for between group comparison.

**Table 3: STATISTICAL RESULT OF INDIVIDUAL ASSESSEMENT CRITERIA**

<table>
<thead>
<tr>
<th>Assessment Criteria</th>
<th>Group</th>
<th>BT MEAN</th>
<th>AT MEAN</th>
<th>M.D</th>
<th>%</th>
<th>S.D</th>
<th>S.E</th>
<th>t-VALUE</th>
<th>p-VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hrit-Kanta Daha</td>
<td>A</td>
<td>1.900</td>
<td>0.250</td>
<td>1.650</td>
<td>86.8%</td>
<td>0.671</td>
<td>0.150</td>
<td>11.00</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>1.800</td>
<td>0.200</td>
<td>1.600</td>
<td>88.9%</td>
<td>0.503</td>
<td>0.112</td>
<td>14.236</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Tikta-Amla Udgara</td>
<td>A</td>
<td>1.900</td>
<td>0.400</td>
<td>1.500</td>
<td>78.9%</td>
<td>0.513</td>
<td>0.115</td>
<td>13.077</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>2.050</td>
<td>0.350</td>
<td>1.700</td>
<td>82.9%</td>
<td>0.733</td>
<td>0.164</td>
<td>10.376</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Avipaka</td>
<td>A</td>
<td>1.350</td>
<td>0.100</td>
<td>1.250</td>
<td>92.6%</td>
<td>0.716</td>
<td>0.160</td>
<td>7.804</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>1.250</td>
<td>0.000</td>
<td>1.250</td>
<td>100%</td>
<td>0.851</td>
<td>0.190</td>
<td>6.571</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Klama</td>
<td>A</td>
<td>0.500</td>
<td>0.150</td>
<td>0.350</td>
<td>70%</td>
<td>0.489</td>
<td>0.109</td>
<td>3.199</td>
<td>p&lt;0.005</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.500</td>
<td>0.200</td>
<td>0.500</td>
<td>100%</td>
<td>0.513</td>
<td>0.115</td>
<td>4.359</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Utklesha</td>
<td>A</td>
<td>1.250</td>
<td>0.100</td>
<td>1.150</td>
<td>92%</td>
<td>0.671</td>
<td>0.150</td>
<td>7.667</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>1.100</td>
<td>0.050</td>
<td>1.050</td>
<td>95%</td>
<td>0.759</td>
<td>0.170</td>
<td>6.185</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Gourava</td>
<td>A</td>
<td>0.500</td>
<td>0.000</td>
<td>0.500</td>
<td>100%</td>
<td>0.513</td>
<td>0.115</td>
<td>4.359</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.200</td>
<td>0.000</td>
<td>0.200</td>
<td>100%</td>
<td>0.410</td>
<td>0.0918</td>
<td>2.179</td>
<td>p&lt;0.05</td>
</tr>
<tr>
<td>Aruchi</td>
<td>A</td>
<td>1.550</td>
<td>0.150</td>
<td>1.400</td>
<td>90.3%</td>
<td>0.754</td>
<td>0.169</td>
<td>8.304</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>1.800</td>
<td>0.100</td>
<td>1.700</td>
<td>94.4%</td>
<td>0.571</td>
<td>0.128</td>
<td>13.309</td>
<td>p&lt;0.001</td>
</tr>
</tbody>
</table>

**DISCUSSIONS ON RESULTS**

**EFFECT OF TREATMENT ON HRIT-KANTA DAHA**
The effect of treatment on *Hrit-Kanta Daha* within the Group, before treatment and after treatment, before treatment and during treatment, the p value <0.001 was highly significant in both the Groups. The Percentage wise relief on *Hrit-Kanta Daha* in Group B was 82.9% and in Group A 78.9%.

**EFFECT OF TREATMENT ON TIKTA-AMLA UDGARA**
The effect of treatment on *Tikta-Amla Udgara* within the Group, before treatment and after treatment, before treatment and during treatment, the p value <0.001 was highly significant in both the Groups. The Percentage wise relief on *Tikta-Amla Udgara* in Group B shows 88.9% and 86.8% in Group A.

**EFFECT OF TREATMENT ON AVIPAKA**
The effect of treatment on *Avipaka* within the Group, before treatment and after treatment, before treatment and during treatment, the p value <0.001 was highly significant in both the Groups. The Percentage wise relief on *Avipaka* in Group B was 100% and 92.6% in Group A.

**EFFECT OF TREATMENT ON KLAMA**
The effect of treatment on *Klama* within the Group, before treatment and during treatment, before treatment and after treatment, the p value <0.001 and <0.005 was highly significant in both the Groups. The Percentage wise relief on *Klama* in Group B shows 100% and 70% relief in Group A.

**EFFECT OF TREATMENT ON UTKLESHA**
The effect of treatment on *Utklesha* within the Group, before treatment and during treatment, before treatment and after treatment, the p value <0.001 was highly significant in both the Groups. The Percentage wise relief on *Utklesha* in Group B was 95% and 92% relief in Group A.

**EFFECT OF TREATMENT ON ARUCHI**
The effect of treatment on *Aruchi* within the Group, before treatment and during treatment, before treatment and after treatment, the p value <0.001 was highly significant in both the Groups. The Percentage wise relief on *Aruchi* in Group B shows 94.4% and 90.3% relief in Group A.

**EFFECT OF TREATMENT ON GOURAVA**
The effect of treatment on *Gourava* within the Group, before treatment and during treatment, before treatment and after treatment, the p value <0.001 and
<0.042 was highly significant and significant in both the Groups.
DISCUSSION ON THE RESULT OF TREATMENT IN GROUP A AND GROUP B
The effect of Gudadi Modaka and Drakshadi Gutika after treatment showed statistically highly significant results. During the clinical trial, by 15th day itself clinical parameters responded in both the groups.

DISCUSSION ON COMPARATIVE EFFECT OF TREATMENT IN GROUP A AND GROUP B

TABLE 4: 31TH DAY

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Mean (GROUP A)</th>
<th>Mean (GROUP B)</th>
<th>M.D</th>
<th>t-VALUE</th>
<th>p-VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hrit-Kanta Daha</td>
<td>1.650</td>
<td>1.600</td>
<td>0.0500</td>
<td>0.267</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Tikta-Amla Udgara</td>
<td>1.500</td>
<td>1.550</td>
<td>-0.0500</td>
<td>0.230</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Avipaka</td>
<td>1.250</td>
<td>1.250</td>
<td>0.000</td>
<td>0.00</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Klama</td>
<td>0.350</td>
<td>0.500</td>
<td>0.150</td>
<td>0.946</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Utklesha</td>
<td>1.150</td>
<td>1.050</td>
<td>0.1000</td>
<td>0.441</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Gourava</td>
<td>0.500</td>
<td>0.200</td>
<td>0.300</td>
<td>2.042</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Aruchi</td>
<td>1.400</td>
<td>1.550</td>
<td>0.150</td>
<td>0.737</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

The result obtained after treatment in both groups was compared by unpaired t test. The test revealed that there is no significant difference between the effects of treatment in both the Groups except in Gourava (AT30).
OVERALL GROUP WISE RELIEF ON 45 TH DAY (FOLLOW UP)
In Follow up, there was a re-occurrence of symptoms Tikta-Amla Udgara and Utklesha in Group A (6 patients) in which Nidana contributed to one patient and in others, it may be suggesting to increase the duration of intervention.

DISCUSSION ON MODE OF ACTION
Drugs which possess the properties like tikta-madhura rasa, madhura vipaka, sheetha virya, laghu Guna with pitta-kaphahara and agnikara karma will help in the management of Amlapitta. Gudadi Modaka and Drakshadi Gutika are mentioned and specially indicated in Amlapitta. Gudadi Modaka contains Pippali, Haritaki, Guda and Drakshadi Gutika contains Draksha, Haritaki and Sita which having the properties like Pitta shamaka, dipana – pachana and agnivardaka.

Mode of Action of Gudadi Modaka
The drugs are ushna virya which causes agni deepana effect and katu rasa by virtue of its agni deepana property helps in management of Amlapitta. Maximum drugs have madhura vipaka and it is said to be pitta shamaka and vatanulomana. The madhura vipaka pacifies pitta so that amlata and dravata of pitta dosha does not aggravate, so the process of agnimandya eliminates out as consequently defective rasa dhatu does not form. Also madhura rasa has got a soothing effect on the body tissues and helps in the production of fresh and healthy tissues. On the basis of 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. All the contents are laghu and ruksha in property. There is increase of drava guna in Amlapitta. Kledaka kapha and pachaka pitta are drava in dominancy. So laghu, ruksha guna performs the function of drava shoshana. Other functions of laghu, ruksha guna are lekhana, sthambhana and ropana.

Mode of Action of Drakshadi Gutika
Drakshadi Gutika is combined formulation prepared by draksha having madhura rasa, madhura vipaka, sheeta veerya and mrudu Guna. Haritaki having lavana varjita pancha rasa kashaya pradhana, madhura vipaka, Vikrutadosh anulomana, aamapachana, and Sita having madhura rasa, sheetaveerya, trupti karaka, indriyaprasadaka. These factors exhibit Pitta shamanaka, and Pitta rechana property. The combination of three drugs i.e. Draksha, Haritaki, and Sita. The Draksha as an individually or in combination with remaining drugs exhibits the pitta
rechana property and it is easily available and palatable, the Haritaki is Lavanavarjita Pancharasa, and Haritaki does Vatanulomana, and also Pathya,Sita more palatable.Tikta rasa of Haritaki is also having properties like Deepana, Pachana, Rechaka which are essential in the management Amlapitta. Madhura rasa of drugs are having sheeta,snigdha and guru properties which antagonize the ushna, tikshna and laghu gunas of pitta dosha. Madhura vipaka of Draksha, Haritaki, Sita acts as Pitta Shamaka, which acts mainly on symptoms like Hrit-Kanta daha, utklesha, Tikta-Amla Udgara, Avipaka, Aruchi and Ushna virya of Haritaki acts as deepana pachana which is useful in Avipaka, Klama, Aruchi. Haritaki acts as Vataanulomana thus helps in elimination of Pitta.Yogavahi guna of pippali enhances the properties of other drugs.

**TIME OF ADMINISTRATION:**

**PRAGBHAKTA** (BEFORE FOOD)

Pragbhakta is preferred in the case of Apana Vata Vaigunya like Indigestion,Constipation, Diarrhea etc. Drugs that are administered before food reach the large intestine, so the drug will able to bring their therapeutical action safely. Mainly deepana-Pachana drugs are administered in Pragbhakta which will digest fast and imparts strength to the body. The bheshaja intake is followed by ahara thus the first target of is Agni and the bheshaja directly acts on Amashaya and eradicates the Vitiated Dosha.

**ACTIVE PRINCIPLES**

**HARITAKI**

- The purgative principle in the pericarp of the fruit has been found due to Glycoside. The major phenolic compounds of the alcohol extracts were confirmed as Tannins - strong antioxidants.

**DRAKSHA**

- Procyanidines- in addition to scavenging free radicals, strongly and non-competitively inhibit xanthine oxidase activity. Procyanidin B4, catechin, and gallic acid at low concentrations (10mol/l, 25 mol/l) were reported to be good cellular preventive agents against DNA oxidative damage.(>150MOL/L –Cellular damage)

**PIPPALI**

- Ethanolic Extract of Piperine-acts on intestinal disorders. Piperine, an alkaloid of Pippali inhibit the gastric emptying (gastric emptying inhibitory activity) and Ethanolic extract of Piperine alkaloid also having strong Anti-depressant action.

**CONCLUSION**

1. In Brihattrayi, Amlapitta has not been considered as a separate disease entity but the complete description of Nidana, Samprapti, Lakshana, and Its Chikitsa Sutra was first explained by Acharya Kashyapa then by Madhava.
2. Present lifestyle that has disturbed the food habits gives rise to agnimandya, vidagdhaajirna and further leads to Amlapitta. The stressful life situations happening nowadays are having a very serious role to play, in the pathogenesis of Amlapitta.
3. In the present clinical trial, Group A and Group B result shows that the effect of both treatment produced highly significant results for subjective parameters Hrit-Kanta Daha,Tikta-Amla Udgara,Avipaka,Aruchi,Utklesha,Klama and Gourava.
4. After analysing the study,observation,clinical trials, results and discussion, it can be concluded that both Gudadi Modaka and Drakshadi Gutika provided better relief in all the symptoms of Amlapitta.
5. The severity of Hrit-Kanta Daha,Tikta-Amla Udgara,Utklesha,Klama,Avipaka,Gourava and Aruchi markedly reduced in both the groups which is statisctically significant and while comparing the both groups, there is no significant difference in the effect on symptoms except in Gourava - after treatment(after 30th day),was more effective in Group A than Group B.
6. Clinically, it was found that Drakshadi Gutika (Group B) is giving immediate effect in severity of symptoms during the 7th day while comparing with Gudadi Modaka (Group A) but in After treatment (after 30th day) the relief in severity of symptoms that was found in the both groups were same.

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