

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

Archana A. V¹, Susheel 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 *pittaprakopaka nidana* leads to *Amlapitta* with the symptoms *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*, 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 *vidagdhata* 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.*⁴

*Gudadi Modaka*⁵ and *Drakshadi Gutika*⁶ 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 please italicize all hindi terms

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, Hritdaha, Kantadaha* with or without the presence of other *lakshanas* of *Amlapitta*.

1. *Tikta-udgara*
2. *Amla-udgara*
3. *Hritdaha*
4. *Kantadaha*
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.
6. Systemic disorders which interferes course of treatment.

METHOD OF MEDICINE PREPARATIONS⁷

GUDADI MODAKA

TABLE 1: INGREDIENTS OF *GUDADI MODAKA*

<i>Pippali</i>	Piper Longum	1 Part
<i>Haritaki</i>	Terminalia Chebula	1 Part
<i>Guda</i>	Jaggery	1 Part

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 warmness 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*

<i>DRAKSHA</i>	VITIS VINIFERA	1 PART
<i>HARITAKI</i>	TERMINALIA CHEBULA	1 PART
<i>SITA</i>	SUGAR CANDY	2 PART

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 mortar 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 days of treatment to assess the progress.

Follow up -15 Days after the course of treatment.

Total study duration - 45 days.

ASSESSMENT CRITERIA:

The general condition of the Patients before Treatment was noted by thorough screening of the *Lakshanas*, detailed history and Physical examinations. Later the changes in *lakshana* after treatment were noted and both the finding was documented in a specially designed Case Proforma. The improvements were assessed through Subjective Parameters by adopting Standard Method of Scoring. Grading was given to all the *Lakshanas* according to the severity and was

documented before, during treatment, after treatment and after follow up.

STATISTICAL ANALYSIS

Post –therapeutic effect of the administered drug is assessed by Paired ‘t’ test. Comparative study of each Subjective parameter of either groups by Student ‘t’ test. For all the tests, a P Value of <0.05 is considered as the statistical significance level for obtaining accurate result.

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 *Pittaprapakopa 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
- Student 't' test is applied for between group comparison.
- Pre-Post Comparison done by Paired 't' test.

Table 3: STATISTICAL RESULT OF INDIVIDUAL ASSESSEMENT CRITERIA

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

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

SYMPTOMS	MEAN		M.D	t - VALUE	p- VALUE
	GROUP A	GROUP B			
HRIT-KANTA DAHA	1.650	1.600	0.0500	0.267	p>0.05
TIKTA-AMLA UDGARA	1.500	1.550	-0.0500	0.230	p>0.05
AVIPAKA	1.250	1.250	0.000	0.00	p>0.05
KLAMA	0.350	0.500	-0.150	0.946	p>0.05
UTKLESHA	1.150	1.050	0.1000	0.441	p>0.05
GOURAVA	0.500	0.200	0.300	2.042	p <0.05
ARUCHI	1.400	1.550	-0.150	0.737	p>0.05

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* in Ayurvedic literature possess the same qualities. The formulation *Gudadi Modaka* contains *Pippali, Haritaki, Guda* and *Drakshadi Gutika* contains *Draksha, Haritaki and Sita* which having the properties like *Pitta shamaka, dipana – pachana and agnivaradaka*.

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 shamana,* 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 be able to bring their therapeutic action safely. Mainly *deepana-Pachana* drugs are administered in *Pragbhakta* which will digest fast and impart 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

HARITAKI⁸ - 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.

DRAKSHA⁹ - 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)

PIPPALI¹⁰ - 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 *Brihatrayi*, *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, vidagdhajirna* 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 statistically 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.

REFERENCES

1. Internet Source-Wikipedia, www.nhealthfacts.org.
2. *Acharya Agnivesha, Charaka Samhita*, Edited by *Vaidya Jadavaji Trikamji Acharya*, Published by *Chaukhamba Surbharati Prakashan* Edition: Reprint 2008, *Chikitsa Sthana*, 15th Chapter.
3. *Sushruta, Sushruta samhitha* with the *Nibandhasangraha Commentary of Sri Dalhanaacharya* Edited by *Vaidya Jadvi Trikamji Acharya*, Published

- by Varanasi: Krishnadas Academy; 1980. Page No: 272 Sutra sthana, 21st chapter.
4. Madavanidana of Madhavakara, Sanskrit Text and Madhukosa Commentary with English Translation by Dr. Himasagara Chandra Murthy, Published by Chaukhambha sanskrit series office voll 2, uttarardha, Amlapitta Nidana 51st chapter.
 5. Yoga Ratnakara, Sanskrit Text with English Translation and edited by Dr. Madham.Shetty,suresh babu, Published by Chaukhambha publication, edition First 2008,Amlapitta Chikitsa 33-34,Page No:973.
 6. 6.Chakradutta, Sanskrit Text with English Translation by P.V. Sharma,Published by Chaukhambha publication,Varanasi,3rd Edition 2007,Amlapitta Chikitsa 52/22,Page:415.
 7. IAMJ-International Ayurvedic Medical Journal K.S.Manjunatha, Shankar Gowda, M.S. Doddamani, Ayurvedic Formulation, Vati Kalpana–A Review June, 2017,Page NO-2022-2025.
 8. www.ajpct.org, Savitha Thirumoorthiswamy, Department of Microbiology, American Journal of Phytomedicine and Clinical Therapeutics, Review Article on Pleiotrophic Evaluation of Haritaki, Published in 2014.
 9. www.ijsr.net International Journal of Science and Research (IJSR), Dr. Nidhi Garg,Dr. Akhil Jain, Therapeutic and Medicinal Uses of Draksha - A Review,Page No-2365-2369.
 10. www.iamj.in International Ayurvedic Medical Journal, Ashalatha M, Rekha B Sannappanawar, A Review Article On Pippali (Piper Longum Linn) Page No-2841-2849.
-

Source of Support: Nil

Conflict Of Interest: None Declared

How to cite this URL: Archana A. V & Susheel Shetty: A Comparative Clinical Study To Evaluate The Efficacy Of Gudadi Modaka And Drakshadi Gutika In Amlapitta. International Ayurvedic Medical Journal {online} 2019 {cited August, 2019} Available from: http://www.iamj.in/posts/images/upload/1286_1292.pdf