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Research Article

CLINICAL STUDY ON COMPARATIVE EFFECT OF *KHANDAMALAKI RASAYANA* AND *GUDAKUSHMANDAKA RASAYANA* IN *URDWAGA AMLAPITTA*

Hosur Chaitrika[1]*, Belavadi S.N[2]

*[1]P.G. Scholar, [2]Professor and HOD Dept. of Kayachikitsa, DGM Ayurvedic Medical College, Gadag, India.

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ABSTRACT

Amlapitta is one of the most common disorder of the *Annavaha Srotas* (digestive System). Improper food intake, changed diet pattern and mental stress are the main contributing factors for disease manifestation. Among two types of *Amlapitta, Urdwaga Amlapitta* is most common in clinical practice. *Amlodgara* (sour belching), *Urodaha* (burning sensation), *Hrillasa* (nausea) are the major symptoms of it. The disease can be co-related with the hyperacidity, hyperchlorhydria or gastritis. Complications caused by the regular use of Modern medicine for the disease encouraged the current study.

Clinical trial of *Khanadamalaki Rasayana* and *Gudakushmandaka Rasayana* is conducted on 40 subjects of *Urdwaga Amlapitta* in two divided groups i.e., Group A and Group B. Single Blind Study Design was applied for the study. Patients were selected from OPD of DGM Ayurvedic Medical College and Hospital for respective trial. Criteria of assessment are set aside on the basis of relief in the signs and symptoms of subjective parameter of *Urdwaga Amlapitta.* Among 40 patients 8 patients got moderate relief and 32 patients got complete relief from the Symptoms by the treatment. Conclusively the treatment was satisfactorily effective in the patients. The criteria of the assessment and Statistical analysis reveal that *Gudakushmandaka Rasayana* is more effective than *Khandamalaki Rasayana* in treating the *Urdwaga Amlapitta*. The drugs used in this study are having the properties of *Pittashamana* and *Rasayana*, So these are helpful in curing the disease along with correcting the *Agni* and general condition of the patient.

INTRODUCTION

Brahatrayees have not explained *Amlapitta* as the *Swatantra Vyadhi* (independent Disease). Charaka explain *Amlapitta* as symptom of *Pittaja Grahani.* [1] In many context symptoms of *Amlapitta* is explained in different terminologies. Kashyapa was the pioneer to explain the disease as a separate entity.[2] He gives the detailed description of the disease along with the treatment. Madhavakara explains *Nidanapanchaka* (Pathophysiology) of the disease[3]. Gastritis, Hyperacidity and non–ulcer dyspepsia may correlate with *Urdwaga Amlapitta*.

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In modern science this ailment is managed with antacids, anti-ulcers and anti-secretary drugs.[4] Antacids neutralize gastric acid which is the first line of immunity. Continuous use makes the person to become more prone to various infections. Ranitidine is most common using drug which comes under H2 blockers. But these drugs are having several ill effects like skin rash, headache, constipation etc FDA requested all Ranitidine products to be pulled from market immediately as it contains uncovered level of NDMA (N-Nitrosodimethylamine) a probable human carcinogen. Other groups of antacids are Proton pump inhibitors Eg: Omeprazole. FDA– U.S Food and Drug Administration warned that there is increased risk of fractures by using this group of drugs often.

Amlapitta may lead to several diseases if not successfully treated. Acharya Gananatha Sena explains that *Grahani* is going to manifest as the *Upadrava* (complication) of the *Amlapitta* if not treated. It may also leads to the severe conditions like *Parinamashoola* which is compared to Peptic ulcers if not get treated. It

is necessary to correct the *Agni* and break the *Samprapti* (pathology) to cure the disease and prevent further complications with the use of proper medicines.

As the disease is involving improper dietary habits as main cause, it takes more time bring a good change in it. As digestion hampered in the disease process there will be mal absorption of nutrients and improper nourishment of the body. By keeping all these in a mind *Khanadamalaki Rasayana* and *Gudakushmandaka Rasayana* explained in *Bhaishajya Ratnavali* are selected for the study.[5,6] Along with relief of symptoms adding the long standing effect of treatment and achieving proper nourishment was the idea behind choosing these formulations in the study.

AIMS AND OBJECTIVES

To evaluate the comparative efficacy of *Khandaamalaki Rasayana* and *Gudakushmandaka Rasayana* in *Urdwaga Amlapitta*.

MATERIALS AND METHODS

Sources of Data

Patient Sources: Patients suffering with the signs and symptoms of *Amlapitta* selected from O.P.D and I.P.D of D.G.M. Ayurvedic Medical College and Hospital, Gadag and free medical camps conducted after fulfilling the inclusion and exclusion criteria.

Selection of Drugs

Drug Sources: The trial drugs collected from local areas and market after being properly identified by the botanist and Dravyaguna teachers.

Method of Collection of Data

Study Design: A single blind comparative clinical study.

Sampling Method: Simple Random Sampling Technique.

Sample Size & Grouping: A minimum 40 patients suffering from *Amlapitta* selected and made into two groups. Group A- 20 patients and Group B- 20 patients.

Posology: *Amalakyadi Churna* 3 grams, two times before food for 4 days with *Sukoshnajala* (warm water) *Haritakyadi Yoga*, 10grams with *Ushnodaka* (hot water), 5th Day, at night single dose as *Koshtashodhana*. *Khandaamalaki Rasayana* 10grams two times before food is given for Group A, and *Gudakushmandaka Rasayana* 10grams two times before food. For both groups *Dugadha* (milk) is used as *Anupana*. Duration was 30 days.

Study Duration

- *Amapachana* for 4 Days.
- *Koshtashodhana* 1 day.
- *Khandaamalaki Rasayana* 30 days in group A
- *Gudakushmandaka Rasayana* 30 days in group B
- Follow up 15 days.
- Total study duration 50 days.
- (Patients assessed on 20th, 35th, 50th day)

Inclusion Criteria

1. Patients having the classical symptoms of *Urdwaga Amlapitta* like *Amla* and *Tiktodgara* (sour belching), *Urodaha* (burning sensation in chest), *Aruchi* (anorexia), Chardi (vomiting), *Shirashoola* (headache), *Klama* (tiredness), *Avipaka* (indigestion), *Gourava* (heaviness) will be selected.
2. Patients of age group between 20-60 years of either sex below 5 years of chronicity.

Exclusion Criteria

1. Patients suffering from *Parinamashoola* and *Annadrava shoola*.
2. Pregnant woman and lactating mother.
3. Patients having major medical or surgical illness.
4. Patients with history of systematic illness like diabetic mellitus, hypertension, endocrine disorder, cardiac pathology, and immune deficiency disorders like AIDS will be excluded.

Criteria For Diagnosis

Diagnosis is made on the basis of classical symptoms and presence of prominent features of *Amlapitta*.

Criteria for Assessment

Assessment is done according to the changes in the subjective parameter before treatment and after treatment. The statistical analysis was done using paired 't' test and S.D, S.E and P value were calculated.

Subjective Parameter

1. *Amlodgara*
2. *Urodaha*
3. *Hrillasa*
4. *Shirashoola*
5. *Bhrima*
6. *Trishna*

Investigations

1. Hb
2. CBC
3. Urine Routine

Grading Criteria

Table 1: Showing the grading criteria of the assessment parameters

Subjective Parameter	Grading	Subjective Parameter	Grading
Amlodgara	Grade 0 – Absent	***Shirashoola***	Grade 0 – Absent
	Grade 1 – Occasional		Grade 1 – Occasional
	Grade 2 – Once in a week		Grade 2 – Once in a week
	Grade 3 – Once in 2-3 day		Grade 3 – Once in 2-3 day
	Grade 4 – Everyday		Grade 4 – Everyday
Urodaha	Grade 0 – Absent	***Bhrima***	Grade 0 – Absent
	Grade 1 – Occasional		Grade 1 – Occasional
	Grade 2 – Once in a week		Grade 2 – Once in a week
	Grade 3 – Once in 2-3 day		Grade 3 – Once in 2-3 day
	Grade 4 – Everyday		Grade 4 – Everyday
Hrillasa	Grade 0 – Absent	***Trishna***	Grade 0 – Absent
	Grade 1 – Occasional		Grade 1 – Occasional
	Grade 2 – Once in a week		Grade 2 – Once in a week
	Grade 3 – Once in 2-3 day		Grade 3 – Once in 2-3 day
	Grade 4 – Everyday		Grade 4 – Everyday

Assessment of Result: The Subjective parameters of base line data to post medications as mentioned above were compared for assessment of result. All the results were analyzed statistically.

OBSERVATION AND RESULT

Total 43 subjects of *Amlapitta* were registered. Out of which 40 patients completed the treatment. 3 subjects dropped out in between the treatment. 2 patients discontinued the treatment as they are unable to complete the follow up. One patient skipped the treatment as he got transferred from the place. Other 40 patients completed the treatment.

Table 2: Showing Effect of therapy on Subjective Parameters in Group A

S No.	Parameter	No.	Mean BT	Mean AT	Reduction Rate	S.D	S.E	T value	P value
1.	*Amlodgara*	20	3.800	0.300	92%	0.513	0.115	30.51	0.00
2	*Urodaha*	20	2.750	0.350	87.2%	1.569	0.351	6.84	0.00
3	*Hrillasa*	20	3.450	0.200	94.2%	0.910	0.204	15.96	0.00
4	*Shirashoola*	20	2.000	0.200	90%	1.436	0.321	5.60	0.00
5	*Bhrima*	20	0.050	0.000	100%	0.223	0.050	1.00	0.330
6	*Trishna*	20	0.350	0.000	100%	0.089	0.244	1.44	0.167

Table 3: Showing Effect of therapy on Subjective Parameters in Group B

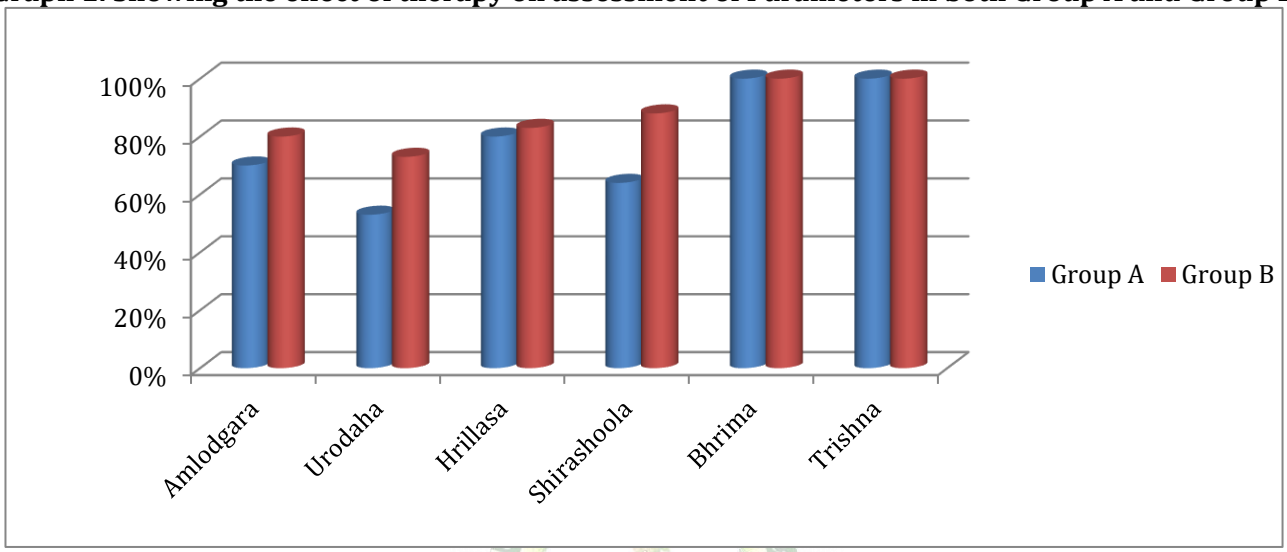
S No.	Parameter	No.	Mean BT	Mean AT	Reduction Rate	S.D	S.E	T value	P value
1.	*Amlodgara*	20	3.200	0.200	93%	1.124	0.251	11.94	o.ooo
2	*Urodaha*	20	3.500	0.250	92.8%	0.786	0.176	18.48	o.ooo
3	*Hrillasa*	20	2.500	0.100	96%	1.231	0.275	8.72	o.ooo
4	*Shirashoola*	20	1.950	0.100	94%	1.226	0.274	6.75	o.ooo
5	*Bhrima*	20	2.500	0.000	100%	0.494	0.099	2.52	0.021
6	*Trishna*	20	0.300	0.000	100%	0.979	0.219	1.37	0.186

*BT – Before Treatment *AT – After Treatment *S.D – Standard Deviation * SE – Standard error

Table 4: Showing the effect of therapy on assessment of Parameters in both Group A and Group B

Parameters	Group A	Group B
Amlodgara	70%	80%
Urodaha	53%	75%
Hrillasa	80%	83%
Shirashoola	64%	88%
Bhrima	100%	100%
Trishna	100%	100%

Graph 1: Showing the effect of therapy on assessment of Parameters in both Group A and Group B



Comparative Efficacy of Therapy Between Group A and Group B using Unpaired "t" Test

Ho - *Khandaamalaki Rasayana* and *Gudakushmandaka Rasayana* are not effective in *Urdwaga Amlapitta*.

H_1 - *Khandaamalaki Rasayana* is more effective than *Gudakushmandaka Rasayana* in *Urdwaga Amlapitta*.

H_2 - *Gudakushmandaka Rasayana* is more effective than *Khandaamalaki Rasayana* in *Urdwaga Amlapitta.*

To accept one of the hypotheses among three, we have to find the "t" value using the statistical Unpaired student "t" test.

Table 5: Showing Statistical analysis between the groups after treatment. (unpaired 't' test)

S No	Parameter	No.	Mean	S.D	S.E	T value	P value	Remarks
1.	*Amlodgara*	40	0.500	1.192	0.267	1.88	0.076	Not Significant
2	*Urodaha*	40	0.850	1.565	0.350	2.43	0.025	Significant
3	*Hrillasa*	40	0.850	1.53	0.342	2.48	0.023	Significant
4	*Shirashoola*	40	0.050	1.731	0.387	0.13	0.899	Not Significant
5	*Bhrima*	40	0.200	0.523	0.117	1.71	0.104	Not Significant
6	*Trishna*	40	0.050	1.538	0.344	0.15	0.886	Not Significant

By doing statistical analysis in Between the Groups after treatment done by Minitab-19 statistical software shows following results:

Amlodgara shows 't' value of 1.88 and 'p' value 0.076 i.e., >0.05 which is not significant.

Urodaha shows 't' value of 2.43 and 'p' value 0.025 i.e., <0.05 which is significant.

Hrillasa shows 't' value of 2.48 and 'p' value 0.023 i.e., <0.05 which is significant.

Shirashoola shows 't' value of 0.13 and 'p' value 0.899 i.e., >0.05 which is not significant.

Bhrima shows 't' value of 1.171 and 'p' value 0.104 i.e., >0.05 which is not significant.

Trishna shows 't' value of 0.15 and 'p' value 0.886 i.e., >0.05 which is not significant.

Thus, Group B is more effective than Group A in *Urdwaga Amlapitta*. Hypothesis 2 is proven.

Table 6: Showing the Overall Assessment

BT-AT/BT×100	Group A		Group B		Total	
	No. of patients	%	No. of patients	%	No. of patients	%
Complete relief	15	75%	17	85%	32	80%
Moderate relief	05	25%	03	15%	08	20%
Mild relief	00	00%	00	00%	00	00%
No relief	00	00%	00	00%	00	00%
Total	20	100%	20	100%	40	100%

DISCUSSION

Amlapitta is a disease which causes mainly due to the improper food habits. Due to *Nidhana Sevana* (intake of causative factor) there will be *Agni vikrati* (Impairment of digestion). This leads to *Avipaka* and *Ama* formation. Because of this there will be poor appetite and improper nourishment of the *Dhatus*. *Rasayana Prayoga* is going to increases the *Agni bala* and thus corrects the basic pathology of the disease as well as nourishes the all the other *Dhatus*. It repairs the walls of stomach damaged due to the excessive gastric enzymes. As *Amlapitta* is having tendency to reoccur with food habits, long time use of antacids may cause some serious side effects. So *Rasayana* in this case helps to relieve the symptoms as well as to achieve *Rasayana* effect.

Khandaamalaki Rasyana is described in *Bhaishajya ratnavali Shoolaadhikara* and *Gudakushmandaka* is mentioned in *Bhaishajya ratnavali Vaajikaranaadhikara*. The ingredients in *Khandaamalaki* are *Amalaki, Kushmanda. Khanda Sharkara* and *Trikatu, Chitraka, Dhanyakaadi Prakshepaka Dravyas*. *Gudakushmandaka Rasayana* is composed of *Guda, Kushmanada Chitraka*, *Trikatu*, *Mustaadi Praksepaka Dravyas*. These ingredients are majorly having *Guru, Sheeta*, *Singda guna, Madhura rasa* and *Sheeta Veerya* and are *Pitta-Vata shamaka*. *Prakshepaka Dravyas* used are having the property of *Deepana* and *Pachana*. They acts on *Annavaha Srotas* majorly and has *Rasayana* Property.

During the observation *Rasyana* effect of the Drugs are noticed in this study. 1 to 2kg of weight is gained in 36 no. of the patient after the treatment. Group B is showing comparatively better result in weight increasing in the patients. *Kushmanda* is having *Balya* and *Brimhana* property and this is one of the reasons to show increased weight after the treatment. Even in investigation Hb and RBCs are raised after the treatment which clearly indicates the effect of *Rasayana* in the participants of the study. Even in this Group B shows maximum result than Group A. *Guda* is rich in iron and hence contribute to the increased level of Hb and RBC. Other *Rasayana Phalashruti* like *Prabha* (complexion), *Varna Prasada* (colour), *Bala* (strength) is also observed in the maximum no. of participants after the completion of the Study.

Discussion on Overall Assessment of Treatment (Table no 5)

After observing the above parameter, the effect of the therapy has been classified as complete relief, moderate relief, and mild relief, and no relief.

From the clinical data out of 40 patients all patients i.e., 100% patients showed responses to treatment.

32 patients i.e., 80% (15 patients from Group A and 17 patients from Group B) showed complete relief.

08 patients i.e., 20% (05 patients from Group A and 03 patients from Group B) showed moderate response.

By assessing over all points it can be said conclusively that *Gudakushmanadaka Rasayana* is proved better over the *Khanadaamalaki Rasayana* in the present study.

CONCLUSION

Amlapitta is the most common disorder of the GI system found in day today practice. It can be correlated to the Hyperacidity and Gastritis. The *Rasayanas* used as *Shamanoushadha* were safe, economical and effective. Symptomatic relief is found in all patients. Treatment showed statistically significant results. No any complications were observed during the course of the treatment. *Rasayana* effects like increase in strength, complexion, Hemoglobin percentage and weight are noticed. The formulations can be used as *Shamanoushadha* and also as *Naimittika Rasayana* in the management of *Urdwaga Amlapitta*.

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***Address for correspondence**
Dr. Hosur Chaitrika
P.G Scholar,
Department of Kayachikitsa,
D.G.M Ayurvedic Medical College and Hospital, Gadag, Karnataka, India.
Email: hosurchaitrika@gmail.com
Phone: 8095298373