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Research Article

A PLACEBO CONTROLLED DOUBLE BLIND COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF *KATUKI* AND *SITA CHURNA* IN *URDHVAGA AMLAPITTA*

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KEYWORDS: *Urdhvagha Amlapitta*, *Katuki* and *Sita churna*, *Placebo*.

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ABSTRACT

The disease *Urdhvagha Amlapitta* is a common functional disease of *Annavaha srotas* due to irregular, improper food habits and busy stressful lifestyle. This disease is a constant challenge to treat because of its recurrence nature due to faulty dietary habits. The management of this disease is somewhat difficult and patients are looking with a hope towards Ayurveda to overcome this challenge. So, this study was designed as a placebo controlled double blind trial to evaluate the efficacy of *Katuki and Sita Churna* capsules in *Urdhvagha Amlapitta.* 30 patients of *Urdhvaga Amalpitta* were selected and randomly allocated in two groups. Group A received *Katuki and Sita* capsules and group B received placebo capsules, both in the dose of two capsules twice daily before food for 30 days. It is observed that *Urdhvagha Amlapitta* is seen in middle age and most common in females. It is usually seen in those whose lifestyle is not fixed and having irregular food habits. All 30 patients had completed the treatment and no adverse effects were reported during the treatment. After statistical analysis the inter group difference were insignificant in all parameters after the end of treatment period except *Hrit/Kanta daha* where in difference was slightly significant with more improvement in group A than the group B. By the overall result we can conclude that *Katuki* and *Sita* capsules are having significant effect in the *Urdhvaga Amlapitta*.

INTRODUCTION

Urdhvaga Amlapitta is a commonly encountering disease of *Annavaha* srotas (GIT) due to *Amlaguna udrikata* of *Pitta* and *Agnidusthi*.[1] In the advancement of busy professional and social life, the change in life style, diet, behavioural pattern, mental stress and strain; human beings are more prone to the disease *Urdhvaga Amlapitta*. Intake of *Viruddha*, *Dustha*, *Amla*, *Vidahi* and *Pitta prakopaka ahara vihara* and *Manasika bhavas*,[2] faulty life style, abrupt and frequent environmental changes, adaptation towards unwholesome foods, etc. significantly aggravates the disease.

Amlapitta may be correlated with Acid Reflex Syndrome which comprises of various types of Gastro-esophageal reflex diseases like Gastritis, Dyspepsia, Heartburn, Peptic ulcer, Hyperacidity, etc. described in Contemporary sciences.[3] *Urdhvaga Amlapitta* is a disease with varied clinical presentation prevalent all over the world, most common in western countries. GERD symptoms occurs at least once a month in 44%, once a week in 20%, and daily in 7% of the adult US population and in India it is likely to be between 8% and 19%, which appears to be similar to that of the western countries.[4] If it is left unattended or neglected may result in to aggravation or may associate with other complication. Contemporary science subjects to symptomatic therapy with antacids, acid suppressers (H_2 receptor antagonists), and proton pump inhibitors. Prolonged use of these medicines may causes ill effects like confusion, diarrhoea, Hypergastrinaemia, headache, skin rashes etc.[5] In Ayurveda the main line of treatment for *Urdhvaga Amlapitta* is *Shodhana*, followed by *Langhana/*

Laghu bhojana and *Agnideepana*.[6] Herbal drug mentioned in *Gada Nigraha* i.e., *Katuki* and *Sita* (*Sheetophala*) is useful in *Amlapitta*.[7] *Katuki* having *Katu Tikta rasa*, *Katuvipaka*, *Sheeta Veerya*, *Ruksha* and *Laghu guna*, *Pitta rechaka*, *Kaphahara* and *Deepana*, *Pachana karma*.[8,9] *Sita* having *Madhura rasa*, *Madhura vipaka*, *Sheeta veerya*, *Vata Pitta Hara*.[10]

Due to *Tridosha shamaka*, *Agnideepaka*, that can be easily administered, and no evidence of having side effects, the present clinical trial is undertaken to evaluate the efficacy of *Katuki* and *Sita churna* in *Urdhvaga Amlapitta*.

Objectives of the Study

To evaluate the efficacy of *Katuki* and *Sita Churna* capsules in the management of *Urdhvaga Amlapitta*.

MATERIALS & METHOD

Research Design

A Placebo controlled double blind comparative clinical trial.

Source of Data

30 patients were selected for the clinical trial and 15 patients were allocated randomly to Group A and Group B respectively.

Method of Drug Preparation

1. *Katuki* and *Sita Churna* capsules

Table 1: Ingredients of *Katuki* and *Sita* capsules

Drug	Quantity
Katuki	1 part
Sita	1 part

Dried, cleaned and best quality root of *Katuki* and *Sita* were subjected to pulverizer to get fine powder separately, and mixed thoroughly both in equal quantity. Then the powder is filled in a capsules of 500mg (size no 0) under the guidance of *Baisajya Kalpana* experts S.V.M.A.M.C. Ilkal. Then prepared capsules are packed in a quantity of 30 capsules in each packet.

2. Placebo Capsules

In a similar manner non digestible starch is also filled in same colored capsules in a same quantity as *Katuki* and *Sita churna* were filled. Then prepared capsules are packed in quantity of 30 capsules in each packet.

Blinding

The prepared capsules were handover to the HOD, Department of *Kaya Chikitsa*. The drugs were blinded and labelled as trial drug 1 and trial drug 2 by the Department of *Kayachikitsa* S.V.M.A.M.C., Ilkal.

Selection of patients

- Patients satisfying the inclusion criteria were selected from OPD and IPD of R.P.K Ayurvedic Hospital Ilkal, irrespective of their sex, caste, religion, occupation and economic status.
- The diagnosed cases of *Urdhvaga Amlapitta* of either sex between age group of 16-60 years were selected for the study.
- A special clinical proforma was prepared, clinical evaluation of subjects were done by collection of data through the information obtained by history, physical findings and clinical examination.
- Patients were included in the study after taking a written consent.

Method of Collection of Data

Patients satisfying the inclusion criteria were selected from OPD and IPD of R.P.K Ayurvedic Hospital Ilkal, irrespective of their sex, caste, religion, occupation and economic status and are randomly allocated in group A and group B respectively.

Diagnostic Criteria

The diagnosis is mainly based on the clinical presentation of the patient according to the symptoms mentioned in classical texts of Ayurveda such as;

Major symptoms[11]

1. *Avipaka*
2. *Tikta /Amla Udgara*
3. *Hrit / Kanta daha*
4. *Utkesha*
5. *Chardi*

Minor symptoms

1. *Klama*
2. *Gourava*
3. *Aruchi*
4. *Shirashoola*

The patients were diagnosed suffering from *Urdhvaga Amlapitta*, those presenting with at least 3 of the major and 2 of the minor complaints.

Inclusion criteria

- Patients diagnosed as *Urdhvaga Amlapitta*, as per diagnostic criteria.
- Patients of age between 16 - 60 years.
- Patients willing to participate in the clinical trial.

Exclusion Criteria

- Patient with poorly controlled hypertension, diabetes mellitus, or patients on prolonged

medications with H_2 blockers, antacids, corticosteroids, antidepressants, etc.

- Patient suffering with Ca. stomach, gastric/duodenal ulcers.
- Pregnant and puerperal women.
- Patients with history of heamatemesis, Melina and other systematic disorders that may interfere with the clinical trial.

Assessment of severity

4 point scale will be used for grading the severity of the individual parameters and over all severity of the condition.

INTERVENTION

Two groups assigned as A and B, were treated with Trial drug 1 and Trial drug 2 respectively.

During trial Period (From 1st – 30th day)

Group A: All 15 patients received trial drug 1 (*Katuki* and *Sita* capsules), 2 capsules (500mg each capsule) twice daily 15-30 minutes before food with luke warm water for 30 days.

Group B: All 15 patients received trial drug 2 (Placebo capsules), 2 capsules (500mg each capsule) twice daily 15-30 minutes before food with luke warm water for 30 days.

Assessment Criteria

The total effect of therapy was assessed considering the overall improvement in signs and symptoms. The obtained results were measured according to the grades given below:

Table 2: Grading of assessment criteria

S.No.	Grade	Percentage
2	Marked Improvement	76 - 100 %
3	Moderate Improvement	51 - 75 %
4	Mild Improvement	26 - 50 %
5	No Improvement	< 25 %

Subjective parameters

Assessment of the following parameters before and after treatment at the end of the follow up.

- *Avipaka*
- *Tikta / Amla Udgara*
- *Hrit / Kanta Daha*
- *Utklesha*
- *Chardi*
- *Klama*
- *Gourava*
- *Aruchi*
- *Shirashoola*

As no objective parameters are available in classical text, assessment was done by only subjective parameters.

Table 2: Shows Grading of Subjective Parameters

Severity ⇨ / ***Laxanas* ⇩**	**(Normal) Grade 0**	**(Mild) Grade 1**	**(Moderate) Grade 2**	**(Severe) Grade 3**
Avipaka	Normal or takes normal time to digest food.	Takes 4-6 hr for digestion of food.	Takes 6-9 hr for digestion of food.	Takes more than 9 hr for digestion of food.
Klama	Absent	For 1-2 hrs, immediate after meal.	Till complete digestion of the food.	Continuous irrespective of digestion.
Utklesh	Absent.	Occasionally but not daily.	Daily and after taking meals (1-2 hr)	Frequently and feels *Amlaasyata* and *Amla-gandha* and reduced after vomiting.
Hrut/ Kanta Daha	Absent	Present only after consumption of *Ushna, Teekshna, Amla padarth*.	Present even with intake of routine meals and relieved only after digestion of food.	Present even with intake of routine meals and relived only by vomiting or antacids.
Tikta/Ama Udghara	Absent.	Present1-5times/day only on consumption of *Amla, Katu, Vidahi padarth*.	Present 6-10 times/ day with normal food, associated with *Hrut/ Kanta daha*.	Present more than 10 times/day even on empty stomach, associated with *Utklesh*.
Gourava	Absent	Occasionally feeling of heaviness	Heaviness remains up to the *Jarana kala* only (4-6 hrs).	Heaviness remains after *Jarana kala* also.
Aruchi	Absent.	*Aruchi* towards	*Aruchi* towards	*Aruchi* towards food.

		food, but can eat.	food. But can eat very little forcibly.	Forcible consumption leads to nausea, and vomiting on occasions.
Chardhi	Absent	Pt vomits 1-2 times in a week.	Pt vomits 3-5 times in a week.	Pt vomits more than 5 times in a week.
Shira shoola	Absent	Occasional, not interfering the daily activities	Occasional, leads to disturbance for daily activity and subsides only after rest.	Continuous, Not relieved by rest and requires active medication for the pain relief.

Statistical Analysis

Results were analyzed statistically by using Unpaired 't' test for individual group and Paired 't' test for comparison of both groups. The data was collected in the form of % of improvement, SD, SE, Probability value ('p' value) and 't' value.

RESULT

Statistical Analysis of all assessment criteria in Group A

Table 3: Showing Statistical Analysis of all assessment criteria in Group A before & after treatment

Criteria	BT	AT	% Improvement	S.D.	S.E.	t value	p value	Interpretation
Avipaka	1.87±0.74	1.20±0.56	35.83	0.49	0.13	5.29	< 0.001	H. S
T/A udgara	2.13±0.92	0.93±0.80	56.34	0.77	0.20	6.00	< 0.001	H. S
H/K daha	2.60±063	1.27±0.70	51.15	0.49	0.13	10.58	< 0.001	H. S
Utklesha	1.47±1.19	0.60±0.63	59.18	0.92	0.24	3.67	0.003	S
Chhardi	0.40±0.83	0.13±0.52	67.50	0.46	0.12	2.26	0.041	S. S
Aruchi	0.67±1.05	0.33±0.62	49.25	0.49	0.13	2.65	0.019	S. S
Gourava	1.73±1.33	0.67±0.82	61.85	0.96	0.25	4.30	0.001	H. S
Klama	1.73±1.16	0.87±0.92	50.29	0.74	0.19	4.52	< 0.001	H. S
Shira shoola	0.87±0.83	0.13±0.35	83.91	0.80	0.21	3.56	0.003	S

Statistical evaluation of all assessment criteria in group A by paired 't' test shows that highly significant results were noticed in *Avipaka, Tikta/Amla udgara, Hrut/Kantha daha, Gorava* and *Klama* with 'p' value <0.001. Significant results were noticed in *Utklesha* and *Shirashoola* with 'p' value <0.01 while in *Chhardi* and *Aruchi* slightly significant results were observed with 'p' value <0.05.

Statistical Analysis of all assessment criteria in Group B

Table 4: Showing Statistical Analysis of all assessment criteria in Group B before & after treatment

Criteria	BT	AT	% Improvement	S.D.	S.E.	t value	p value	Interpretation
Avipaka	1.67±0.82	1.20±0.86	28.14	0.52	0.13	3.50	0.004	S
T/A udgara	1.93±1.10	1.13±0.99	41.45	0.77	0.20	4.00	0.001	H. S
H/K daha	2.20±1.21	1.47±1.06	33.18	0.80	0.21	3.56	0.003	S
Utklesha	1.80±1.01	1.00±0.76	44.44	0.68	0.17	4.58	< 0.001	H. S
Chhardi	0.40±0.51	0.13±0.35	67.50	0.46	0.12	2.26	0.041	S. S
Aruchi	0.40±0.63	0.13±0.35	67.50	0.46	0.12	2.26	0.019	S.S
Gourava	1.07±1.28	0.87±1.06	18.69	0.41	0.11	1.87	0.082	N.S
Klama	2.07±1.03	1.53±0.92	25.60	0.64	0.17	3.23	0.006	S
Shira shoola	1.20±0.86	0.47±0.64	60.83	0.59	0.15	4.78	< 0.001	H. S

Statistical evaluation of all assessment criteria in group B by paired 't' test shows that highly significant results were noticed in *Tikta/Amla udgara, Utklesha* and *Shirashoola* with 'p' value <0.001. Significant results were noticed in *Avipaka* and *Hrut/Kantha daha* with 'p' value <0.01 while in *Chhardi* and

Aruchi slightly significant results were observed with 'p' value <0.05. *Gourava* shows insignificant result with 'p' value >0.05.

Statistical analysis of Inter- group difference in results

Table 5: Statistical status of inter-group difference of changes observed in assessment criteria at the end of treatment i.e. 31st day

Parameters	Mean BT-AT of A	Mean BT-AT of B	Mean difference	SE (±)	't' Value	'p' Value
Avipaka	0.67±0.49	0.47±0.52	0.20	0.183	1.090	0.285
Tikta/Amla udgara	1.20±0.77	0.80±0.77	0.40	0.283	1.414	0.168
Hrut/Kantha daha	1.33±0.49	0.73±0.80	0.60	0.242	2.483	0.019
Utklesha	0.87±0.92	0.80±0.68	0.07	0.294	0.227	0.822
Chhardi	0.27±0.46	0.27±0.46	0.00	0.167	0.00	1.000
Aruchi	0.33±0.49	0.27±0.46	0.07	0.173	0.386	0.703
Gourava	1.07±0.96	0.20±0.41	0.87	0.270	3.207	0.003
Klama	0.87±0.74	0.53±0.64	0.33	0.253	1.316	0.199
Shirashoola	0.73±0.80	0.73±0.59	0.00	0.257	0.00	1.000

The inter group difference in results are insignificant in all parameters when analyzed by unpaired 't' test with 'p' value >0.05 for all the parameters after the end of treatment period except *Hrut/Kantha daha* wherein difference was slightly significant with more improvement in group A as difference in means was 0.60 & 'p' value <0.05.

OVERALL IMPROVEMENT

Table 6: Overall Improvement in assessment parameters of *Urdhvaga Amlapitta* in both groups

Overall Improvement	Group-A		Group-B	
	F	%	f	%
Marked (>75%)	01	11.11	00	0.00
Moderate (51-75%)	05	55.56	03	33.33
Mild (25-50%)	03	33.33	05	55.56
No Improvement (<25%)	00	0.00	01	11.11

Overall assessment of improvement in assessment parameters shows marked improvement in 11.11% parameters, moderate improvement in 55.56% parameters, mild improvement in 33.33% parameters in group A while in group B no parameter shows marked improvement and moderate improvement in 33.33% parameters, mild improvement in 55.56% parameters was seen.

DISCUSSION

Amlapitta is a dominant disorder in the present scenario due to faulty lifestyle and behavioural pattern. After a careful screening and analysis of etiological factors *Nidana* of *Amlapitta* is not only depended on *Aharaja* and *Viharaja* along with *Manasika* and *Agantuja nidanas* also plays major role in disease *Amlapitta*.

By this study we found result of all assessment criteria in Group A and Group B between Before treatment and After treatment showed highly significant effects in 5 parameters i.e., *Avipaka, Tikta amla udghara, Hrit kanta Daha, Gaurava* and *Klama* with *Katuki* and *Sita* capsules in group A and in group B, 3 parameters i.e., *Tikta amla udghara, Utklesha, Shirashoola* with Placebo capsules.

The inter group difference in results are insignificant in all parameters after the end of treatment period except *Hrut/Kantha daha* wherein difference was slightly significant with more improvement in group A which indicates confirmative evidence regarding the therapeutic value of *Katuki* and *Sita* capsules.

The present study aimed to look for an effective, safe and affordable treatment of *Urdhwaga Amlapitta*. However, the herbal combination *Katuki* and *Sita* capsules used in this study showed better improvement in symptoms when compared to placebo. This trial drug was found to be well tolerated with no adverse effects. These beneficial actions of *Katuki* and *Sita* capsules might be due to the properties which possess *Tikta*, *Madhura rasa*, *Laghu Ruksha guna, Sheeta veerya, Katu Madhura vipaka* with *Deepana Pachana karma, Pitta rechaka* and *Tridosha hara* properties.[12] Which established a significant effect on reducing the severity of *Amlapitta* symptoms.

CONCLUSION

The overall result of this study showed moderate improvement in group A (*Katuki* and *Sita* capsules) which may because of effect of drug. At the same time group B (Placebo capsules) showed mild improvement which may because of psychological factor. In this study most of patients having *Madyama satwa*. *Charaka* mentioned in *Satwa Pareeksha* that, in *Madhyama satwa* "Tolerate the pain themselves when they realize that other can also tolerate it, Then at time they gain strength from others".[10] By the same way positive perception of treatment by the patients in Placebo group obtained significant result.

No side effect was encountered during the treatment and after follow up period.

By the overall result we can concluded that *Katuki* and *Sita* capsules are having significant effect in the *Urdhvaga Amlapitta*.

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