



A CLINICAL STUDY TO EVALUATE THE EFFECT OF KATUKA (*PICRORHIZA KURROA* ROYLE EX BENTH.) ON AMLAPITTA

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Abstract

Due to urbanization and changed life style people are inviting many health problems, *Amlapitta* being one among them. It is a common problem of the society in present time, due to irregular and improper food habits, busy and stressful lifestyle. Symptoms like *Kukshidaha*, *Tiktamlodgar*, *Utklesh* etc. cause disturbance in day to day activities of the sufferer. Though *Amlapitta* is not a life threatening disease, if left untreated or neglected, it may invite major health problems. In spite of voluminous work done on *Amlapitta* and its management in *Ayurveda*, it still remains a common problem leading to complications, as in most of the cases no permanent cure is achieved except symptomatic relief to some extent. Hence this disease has been taken for the present study.

Clinical study has been conducted in two groups. In group-II patients the drug *Katuka* has been given along with *Sitopala* (*Anupana*) as per reference "*कटुका सिताश्वलेहा..... 11 Gad Nigraha (38/26)*". But on the basis of pharmacodynamic properties of *Katuka* viz. *Tikta Rasa* and *Sheeta Veerya* which are *Pitta Shamak*, it has been tried singly without the additive effect of *Sitopala* in group-I patients, as *Amlapitta* is a *Pitta* predominating disease. Statistically significant results were found in both the groups. But results were better in group-II as compared to group-I.

Keywords: *Amlapitta*, *Pitta* predominating disease, *Katuka*, pharmacodynamic properties, *Pitta Shamak*.

Introduction

21st century is full of stress requiring more

speed and accuracy. It is the era of competition. Due to which life style, diet pattern and behavioral pattern of people are changed. People are stressed and anxious due to struggle for upcoming into the social scenario that is why neglecting dietary regimen. Also now a days people are attracted to junk food. All of these lead to hampered digestion, causing so many GIT disorders. *Amlapitta* is one among

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them. Indiscriminate use of several therapeutic agents like steroids, NSAIDs and addiction to smoking, alcohol, drinking tea and coffee several times are chiefly associated with this disease. Over workload and mental stress may again aggravate this disease. In *Amlapitta* relapse is very common, as it requires prolonged dietetic control and also it is related to psychological disorders. *Amlapitta* is very distressing due to its chronic, relapsing and remittent nature. So, present clinical trial was conducted to find out a safe and effective management for *Amlapitta*.

OBJECTIVES

1. To analyze the clinical efficacy of drug *Katuka* with and without *Sitopala (Anupan)* on *Amlapitta*.

SELECTION OF PATIENTS

1. Inclusion criteria

Patients willing for trial with

- a) Age - Above 12 years
- b) Sex - Either sex
- c) Diagnosis - On the basis of following symptoms (as per classical texts):
 - *Avipaka* (Indigestion)
 - *Tiktamalavamikadochit* (Occasional sour and bitter vomiting)
 - *Utklesh* (Nausea)
 - *Tiktamlodgar* (Bitter and acidic eructation)
 - *Hritkanthadaha* (Retrosternal burning)
 - *Aruchi* (Loss of Appetite)
 - *Kukshidaha* (Epigastric burning)
 - *Udaraadhman* (Flatulence)
 - *Klama* (Mental fatigue)

2. Exclusion criteria

- a) Patients not willing for trial.
- b) Known case of peptic / duodenal ulcer.
- c) Known case of any major pathology.
- d) Patients of diabetes mellitus.

2. To find out a safe and effective single drug therapy for *Amlapitta*.

Material and Methods

Clinical trial design

A simple randomized single blind clinical study.

Plan of study

The clinical trial was started after the approval from the Chairman of Ethics committee. For the present study 30 patients of *Amlapitta* consenting to participate in the drug trial were selected from O.P.D. of R.G.G.P.G. Ayurvedic Hospital, Paprola. Patients were divided randomly into two groups I and II (15 patients in each group). But 3 patients in group-I and 1 patient in group-II left the treatment against medical advice and did not complete the trial.

LABORATORY INVESTIGATIONS

Estimation of Hb%, TLC, DLC, ESR, FBS, LFT (SGOT, SGPT, S. bilirubin) and

lipid profile were carried out for general assessment of patients and exclusion of other pathologies.

PLAN OF TREATMENT

Patients of group-I and group-II were given following treatment:

Group-I

Katuka Mool (rhizome) *Churna* : Two capsules (each 500 mg) bd
(in capsule form)

Anupana : *Jala*

Group-II

Katuka Mool (rhizome) *Churna* : Two capsules (each 500 mg) bd
(in capsule form)

Anupana : *Sitopala (Mishri)* and *Jala*

Duration of trial : 3 weeks

Follow up : After every week during the trial

Dietary Instructions

Patients were asked to avoid fried and spicy food, *Kulattha*, *Urada*, tea, coffee, alcohol, smoking and other *Pitta Vardhaka Ahara*. Also patients were advised to take their meals at regular time intervals.

Counseling

Counseling was done on every visit to relieve stress and emotional components which may trigger symptoms.

ASSESSMENT CRITERIA**Table No. I: Scoring pattern adopted to assess the symptoms of the disease is as follows:**

Signs & Symptoms	Grading				
	0	1	2	3	4
<i>Avipaka</i> (Indigestion)	No indigestion	Mild indigestion causing no disturbance in day to day activity	Moderate indigestion	Severe indigestion causing disturbance in day to day activity	Severe indigestion causing disturbance in routine activity with occasional diarrhea
<i>Tiktamalavam ikadochit</i> (Occasional sour and bitter vomiting)	No complaint	vomiting occasionally, 1-3 per week, one mouthful in quantity and self-induced	Vomiting after meal or anytime once a day, one handful in quantity	Vomiting after each meal, spontaneous, 4-6 handful or profuse	Vomiting anytime a day, no relation to meal, spontaneous, profuse
<i>Utklesh</i> (Nausea)	Absent	Occasional desire to vomit	Frequent desire to vomit	Regular desire to vomit	Regular desire to vomit with profuse water brash
<i>Tiktamlodgar</i> (Bitter and acidic eructation)	Absent	Occasional complaint	2 or 3 times a day	Frequently	Regular complaint
<i>Hritkanthadah a</i> (Retrosternal burning)	Absent	Occasional complaint of warmth sensation in substernal area, subsides itself.	Warm sensation in substernal area, 1-2 times per day gets relieved by food and water.	Frequent feeling of warmth or burning sensation substernally, gets relieved by taking medicine.	Continuous feeling of warmth or burning sensation substernally, does not relieved by taking medicine
<i>Aruchi</i> (Loss of appetite)	Normal appetite	Mild loss of appetite	Moderate loss of appetite	Severe loss of appetite	Very poor appetite
<i>Kukshidaha</i> (Epigastric burning)	Absent	Occasional burning sensation in abdomen	Burning sensation 3-4 times a day, relieved by water and food	Continuous complaint, relieved by taking medicine	Continuous complaint not relieved by taking medicine

<i>Udaraadhman</i> (Flatulence)	Absent	Occasional feeling of distension or gaseousness in abdomen	Moderate complaint / discomfort	Frequent distended abdomen	Continuous distended abdomen
<i>Klama</i> (Mental fatigue)	No complaint	Mild depression with occasional headache	Moderate depression with stressful condition	Severe stress with heaviness in head and headache, relieved by vomiting	Continuous heaviness in head and headache not relieved by vomiting

Patients were assessed before and after the treatment for improvement in symptoms on the basis of above said scoring pattern and percentage improvement was calculated.

Final Assessment of Results:

Cured	-	100% relief in symptomatology
Markedly improved	-	76-99% improvement in symptoms
Moderately improved	-	51-75 % improvement in symptoms
Mildly improved	-	26-50% improvement in symptoms
Unchanged	-	Below 25% improvement in symptoms

Statistical Analysis

The obtained data was analyzed statistically in terms of mean score before treatment (BT), after treatment (AT), difference of mean (BT – AT), standard deviation (SD) and standard error (SE).

Students paired ‘t’ test and unpaired ‘t’ test were applied at p >0.05, p<0.05, p<0.01 and p<0.001, to observe significance of results obtained after treatment.

Observation

Demographic profile study was conducted on 30 patients and assessment of symptoms was done in 26 patients, as 4 patients dropped the trial.

Out of 30 maximum number of patients i.e. 63.34% were in age group 18-40 years and 70% of patients were females. Service holders and housewives had equal incidence i.e. 33.33%. 86.67% patients had history of eating

spices and chillies with meals, 73.33% patients used to take junk food between meals and 56.67% patients were addicted to tea. 63.33% patients were not having regular timing of food intake. 46.67% patients were stressful and 20% patients were emotional. It was observed that 46.67% patients were of *Vata-Pittaja Prakriti* and 36.67% patients were of *Pitta-Kaphaja Prakriti*. 56.67% patients had *Krura Kostha*. 73.33% patients had previous history of treatment. Out of 26 patients *Avipaka* was present in 84.61%, *Tiktamlavamikadochit* was present in 42.31%, *Utklesha* was present in 76.92% of patients, 84.61% patients had complaint of *Tiktamlodgar*, 88.46% patients had complaint of *Hritkanthadaha*, 100% patients were having complaint of *Kukshidaha*, 76.92% patients had complaint of *Udaraadhman* and 65.38% patients presented with complaint of *Klama*.

Results

Table No. II: Effect of therapy in 12 patients of Group-I (paired t test):

Sr. No.	Symptoms	Mean		% relief		SD±	SE±	't'	p
		BT	AT	Diff.	%age				
1.	<i>Avipaka</i>	2.1	1.0	1.1	52.38%	0.57	0.18	6.13	<0.001
2.	<i>Tiktamlavamikad ochit</i>	1.75	1.0	0.75	42.86%	0.50	0.25	3	>0.05
3.	<i>Utklesh</i>	2.67	1.67	1.0	37.59%	0.50	0.17	6	<0.001
4.	<i>Tiktamlodgar</i>	3.2	2.0	1.2	37.5%	0.42	0.13	9	<0.001
5.	<i>Hritkanthadaha</i>	2.3	1.5	0.8	34.78%	0.42	0.13	6	<0.001
6.	<i>Aruchi</i>	1.56	0.88	0.67	43.22%	0.50	0.17	4	<0.01
7.	<i>Kukshidaha</i>	2.58	1.58	1.0	38.76%	0.60	0.17	5.74	<0.001
8.	<i>Udaraadhaman</i>	2.11	1.11	1.0	47.39%	0.71	0.24	4.24	<0.01
9.	<i>Klama</i>	1.62	1.0	0.62	38.27%	0.52	0.18	3.42	<0.05

Table No. III: Effect of therapy in 14 patients of Group-II (paired t test):

Sr. No.	Symptoms	Mean		% relief		SD±	SE±	't'	p
		BT	AT	Diff.	%age				
1.	<i>Avipaka</i>	2.33	1.0	1.33	57.08%	0.49	0.14	9.38	<0.001
2.	<i>Tiktamlavamik adochit</i>	1.57	0.57	1.0	63.69%	0.87	0.33	3.24	<0.05
3.	<i>Utklesh</i>	2.45	0.91	1.54	62.86%	0.69	0.21	7.45	<0.001
4.	<i>Tiktamlodgar</i>	3.08	1.33	1.75	56.82%	0.75	0.22	8	<0.001
5.	<i>Hritkanthadaha</i>	2.38	0.92	1.46	61.34%	0.78	0.22	6.79	<0.001
6.	<i>Aruchi</i>	1.8	0.8	1.0	55.56%	0.67	0.21	4.74	<0.01
7.	<i>Kukshidaha</i>	2.79	1	1.79	64.16%	0.80	0.21	8.33	<0.001
8.	<i>Udaraadhama n</i>	2.18	0.91	1.27	58.26%	1.01	0.30	4.18	<0.01
9.	<i>Klama</i>	1.89	0.78	1.11	58.73%	0.60	0.2	5.55	<0.001

From above, it is clear that in group-I patients statistically significant results were found for all symptoms except *Tiktamlavamikadochit*. But results were better in patients of group-II than group-I.

Table No. IV: Inter group comparison over criteria of assessment (unpaired t test):

Sr. No.	Symptoms	% Relief		Diff. in %age	SD ±	SE ±	't'	p
		Gr.- I	Gr.- II					
1.	<i>Avipaka</i>	52.38%	57.08%	4.7%	0.53	0.22	1.04	>0.05
2.	<i>Tiktamlavamikadochit</i>	42.86%	63.69%	20.83%	0.77	0.48	0.52	>0.05
3.	<i>Utklesh</i>	37.59%	62.86%	25.27%	0.61	0.27	2	>0.05
4.	<i>Tiktamlodgar</i>	37.5%	56.82%	19.32%	0.62	0.26	2.12	<0.05
5.	<i>Hritkanthadaha</i>	34.78%	61.34%	26.56%	0.65	0.27	2.44	<0.05
6.	<i>Aruchi</i>	43.22%	55.56%	12.34%	0.59	0.27	1.22	>0.05
7.	<i>Kukshidaha</i>	38.76%	64.16%	25.4%	0.71	0.28	2.82	<0.01
8.	<i>Udaraadhaman</i>	47.39%	58.26%	10.87%	0.89	0.40	0.67	>0.05
9.	<i>Klama</i>	38.27%	58.73%	20.46%	0.56	0.27	1.81	>0.05

Thus the difference observed is statistically significant in

- *Tiktamlodgar*
- *Hritkanthadaha*
- *Kukshidaha*

Table No. V: Overall effect of therapy in 26 patients:

Total effect	Gr.- I		Gr.- II		Total	
	No. of pts.	%age	No. of pts.	%age	No. of pts.	%age
Cured	0	0	0	0	0	0
Markedly improved	0	0	4	28.57	4	15.38
Moderately improved	3	25	7	50	10	38.46
Mildly improved	8	66.66	2	14.28	10	38.46
Unchanged	1	8.33	1	7.14	2	7.69

Overall effect of therapy shows that 15.38% patients showed marked improvement, 38.46% patients were improved moderately, again 38.46% patients showed mild improvement.

No adverse effect of the drug was found during the clinical study.

Discussion

Amlapitta is a common disorder of *Annavaha Srotas*. In *Amlapitta*, *Amlta* (sourness) of *Pitta* gets increased, as it becomes *Vidagdha* (undigested/partially digested). Regarding the *Samprapti* of disease, *Acharya Charaka*^I and *Kashyapa*^{II} have said that the disease *Amlapitta* occurs as a result of *Agnimandya*. Due to *Agnimandya* *Vidagdha Paka* of *Anna* takes place, this *Vidagdha Anna* becomes *Shukta* (due to fermentation) in *Amashya* and ultimately it vitiates *Katu Rasa* of *Pitta*. So, *Pitta* becomes *Amla* as *Sushruta* has described *Prakrit Rasa* of *Pitta* as *Katu* while *Vidagdha Pitta Rasa* as *Amla*^{III}, thus causing *Amlapitta*. But *Madhavakar* has explained the disease as an independent clinical entity. *Madhavakar* has stated that the disease occurs directly due to *Pitta Prakopa* (*Amlta Vridhi*) caused by the consumption of *Pitta Vardhak Ahar-Vihar*^{IV}. But if the disease is not treated in this phase and *Pitta* remains *Vidagdha*, then it ultimately leads to *Agnimandya* and a vicious circle is established. So, it is clear that in *Amlapitta* the main aim of treatment should be *Pitta Shaman*, *Deepan* (to cure *Agnimandya*) and *Pachan* (to cure *Vidagdhavastha*).

Probable Mode of Action of *Katuka* on *Amlapitta*

The principle of treatment of a disease is its *Samprapti Vighatana* means to dismantle the *Samprapti Ghatakas* of the disease by the drug. On the basis of this principle the probable

mode of action of the drug *Katuka* on the disease *Amlapitta* has been described as follows:

Probable mode of action of *Katuka* over *Dosha*

Predominant *Dosha* in *Amlapitta* is *Pitta* and *Katuka* is having *Pitta Shamak* effect because of

- *Tikta Rasa*
"जयन्ति पित्तं 'ले'माणं क"ायकदुत्तिका: 11"
(Charaka Sutra 1/66)
- *Sheeta Veerya* - *Sheeta Veerya* of *Katuka* potentiates the *Pitta Shamak* effect of *Tikta Rasa*.

Probable mode of action of *Katuka* over *Dushya*

Dushya of *Amlapitta* are *Annarasa* and *Rasadhatu*. Due to *Agnimandya* at *Jatharagni* level *Annarasa* becomes *Vidagdha* resulting in *Rasadhatu Dushti*. Thus *Deepana Karma* is required.

- *Tikta Rasa* has been described by *Acharya Charaka* as *Deepana*
"तिक्तो रसः दीपनः 11" (Charaka Sutra 26/43)

Tikta though belonging to *Saumaya* group stimulates *Agni* due to its *Vayu Mahabuta* dominating property, which stimulates *Saman Vata* and absorbs the *Kledak Kapha* (excessive mucous secretion) which is responsible for *Mandagni*.

Probable mode of action of *Katuka* over *Srotas* and *Srotodushhti*

Srotas involved in *Amlapitta* are *Annavaha* and *Rasavaha Srotas*. Due to

formation of *Ama* in *Amlapitta Srotas* / passage is blocked. So, *Sang Srotodushti* is found, which also causes *Vimargagaman Srotodushti*.

- *Tikta Rasa* is *Srotoshodhan* i.e. channel cleaning. It clears the *Srotas* by absorbing the fluid and slimy material due to *Vata* and thus vacating the space on account of *Akasha*. Due to *Suksham Guna* of *Akasha Mahabhuta* it permeates even to the minute channels clearing the *Sanga Srotodushti* and *Vimargagaman* is also relieved. As *Acharya* has also described:

bfr äk j l %
Dynerko l ke T t y l h d k i ; Lone = i j h k f i Y k ' y ' e k
i ' k k ' k . k k A A B

(Charaka Sutra 26/43)

Probable mode of action of *Katuka* over *Ama*

- In *Amlapitta* because of *Agnimandya* there is formation of *Ama*, so here *Aampachana Karma* is required. *Tikta Rasa* has been described by *Acharyas* as *Ama Pachaka*.

"तिक्तो रसः पाचकः ॥" (Charaka Sutra 26/43)

To cure *Srotodushti* caused by *Abhishyandi* property of *Ama Shoshan Karma* and to pacify *Vishaktata* of *Ama Vishaghan Karma* is required.

Acharya Charaka has already mentioned these *Karmas* of *Tikta Rasa*.

bfr äk j l % Lo ; e j k f " . k j ! ; j k d " # k fo " k " # d f e " # k
*e % & k h k (d .) d " * r \$. k k + ' k e # L , o) : e k / l ; k %*
f L O k j h d j . k k To j " # k n h i # % i k # L r 1 ; ' k k 2 k # k y 3 k # %
Dynerko l ke T t y l h d k i ; Lone = i j h k f i Y k ' y ' e k i ' k k
" k . k k 5 6 k % ' k h r k y 7 8 A A B

(Charaka Sutra 26/43)

Hence, it can be stated that on the basis of *Tikta Rasa* and *Sheeta Veerya*, the drug is effective to treat *Amlapitta*.

The reason to find better result of the drug with *Sitopala* may be due to its *Madhur Rasa* and *Sheeta Veerya* which are *Pitta Shamak*.

Conclusion

In group-I, no patient was cured and markedly improved, 25% patients were moderately improved, 66.66% patients were mildly improved and 1 patient (8.33%) remained unchanged. On the other hand in group-II, no patient was cured, 28.57% patients were markedly improved, 50% patients were moderately improved, 14.28% patients were mildly improved and 1 patient (7.14%) remained unchanged. Thus it is clear that single drug *Katuka* is effective in treating *Amlapitta* with additive effect of *Anupan Sitopala*. So this study also proves the importance of *Anupan* in Ayurvedic principles of management.

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