Clinical Research

A comparative clinical trial of *Chincha kshara* and *Kadali kshara* on *Amlapitta*

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Abstract

A clinical trial was carried out on 30 patients of Amlapitta aged between 20 to 35 years with complaints of *Avipaka*, *hrit-kanthadaha*, *tikta-amlodgara*, *utklesa*, *udarasula*, *adhmana* and *aruchi*, who were registered from OPD and IPD of Gopabandhu Ayurveda Mahavidyalaya, Puri. They were equally divided into three groups *Chincha kshara, Kadali kshara* and placebo (who were administered with fresh wheat powder) for 30 days in a dose of 500 mg thrice daily with water. Investigations was done in order to exclude upper gastrointestinal tract ulcer, carcinoma in stomach, cholecystitis, carcinoma gall bladder, and heart diseases. The clinical assessments were carried out on the 30th day by subjective and objective parameters and it was inferred that both *Chincha kshara* and *Kadali kshara* were effective and reduced the symptoms of *amlapitta*. *Chincha kshara* was found to be more effective than *Kadali kshara*. The study shows the effect of *Chincha* and *Kadali kshara* which led to cure in 4(40%) and 3(30%) patients respectively, and maximum improvement in 4(40%) and 5(50%) patients affected with *amlapitta* disease, respectively. No untoward effect was noticed due to administration of *ksharas* during the clinical trial period.

Key words: Adhmana, *Amlapitta*, *Chincha kshara*, *Kadali kshara*, *Udarasula*

Introduction

Since time immemorial, India has been endowed with a fairly well-established medical science of its own with rich and genuine materia medica.[1] The treatment knowledge is empirical and obtained by trial and error methods. Today, drugs which are used in medicines are scientifically evaluated and they are either obtained from natural sources or are of synthetic origins. Natural drugs are procured from plants, animals and mineral origins.[2]

Ksharas, a type of Ayurvedic medicine of plant origin, are prepared out of the dried plant ashes by a special process known as *kshara kalpana*.[3] Since the period of Samhita, *ksharas* have been used in the treatment of many diseases. *Ksharas* have the qualities[4] of *tikshna*, *natimridu*, *ushna*, *laghu*, *ruksha*, *pichhila*,[5] *seta* and *shukla*. They possess *Deepana*,[6] *pachana*, *chhedana*, pacify *tridosa*, clears srotas and destroy the *krimis*.[7] Taste of *kshara* is *pancharasa* being *lavana* as *anurasa* and devoid of *amlarasa*.[8] By

asserting the real state of *dosas*, an efficient physician with *kshara* expertise can well treat the patients suffering from *amlapitta*,[9,10] *grahani*, *sula*, *gulma*,[11] *mandagni*, piles, fistula-in-ano[7] and *adhimansa* Judicious administration and application of *kshara*, will always give benefit with full satisfaction.

Amlapitta, may be caused due to irregular food habits and abuse of certain analgesic drugs.

Keeping the above under consideration, a random sample of 30 patients were of *Amlapitta* studied, to evaluate the efficacy of trial drugs. They were equally divided into three groups, and were administered with *Chincha kshara*, *Kadali kshra* and fresh wheat powder as placebo, respectively.

Aim and objective

This study was carried out to evaluate the efficacy of the *Chincha kshara* and *Kadali kshara* and to compare the drug effect on *Amlapitta*.

Materials and Methods

Selection of patients

Thirty patients of *Amlapitta* with age between 20–45 years of

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both sexes were enrolled from OPD and IPD of Gopabandhu Ayurveda Mahavidyalaya, Puri. Detailed history, complete general and systemic examination and required pathological investigations were done.

Inclusion criteria for selection of patients were *avipaka* (indigestion), *hrit-kanthadaha* (heart burn), *tikta-amlaudgara* (acid eructation), *utklesa* (nausea), *vamana* (vomiting), *udarasula* (abdominal pain), and *adhmana* (flatulence), *klama* (tiredness) and *aruchi* (anorexia).

The exclusion criteria was *Nila-krushnaraktavamana* (bile–blood vomiting), *murchha* (syncope), *angapitata* (yellow coloration of body), *krushna-raktamalasarana* (black and blood letting stool), *amasayavrana* (stomach ulcer), *grahanivrana* (duodenal ulcer), *garbhavasta* (pregnancy), lactation, cancer in stomach, *pittasayaasmari* (cholelithiasis) and patients suffering from acid peptic disease for more than 3 years.

Thirty patients were randomly grouped into three groups. Each group consisted of 10 patients and the groups were named as group C, K and P. They were administered with *Chincha kshara* (group C), *Kadali kshara*(group K) and fried wheat powder as placebo (group P) in a dose of 500 mg, respectively, thrice daily with water after food for 30 days. Normal diet devoid of excess *amla*, *lavana* and *katu rasa* was advised. The required pathological investigations were conducted on the day of entry and on 30th day of the clinical study in all the selected patients and recorded for clinical evaluation.

Selection of drug

Classical references impart a very clear concept of the therapeutic use of *kshara* on internal application.[12] When *amla* is predominant,[8] *kshara* is said to be like *agni*[4] and is caustic. It enhances the digestive power by which indigestion, heart burn, acid eructation, nausea and vomiting like symptoms of *Amlapitta* will be subsided. Considering this the *kshara* preparations were included in the clinical study.

The *Chincha* (tamarind)[13] and *Kadali* (plantain)[14] are mentioned under *phalavarga* in classical texts, and the *kshara* prepared[15] out of the tamarind bark and leaves of plantain is advocated in the treatment of *gulma*, *ajeerna*, *mandagni*, *amlapitta*, *adhmana*, etc.[16] The physico-chemical analysis of *chincha kshara* and *kadali kshara* was done at Regional Research Laboratory, Bhubaneswar, to identify the pH, specific gravity, alkalinity and associated elements [Table 1].

Investigations done

Hemoglobin (Hb) estimation in gm%, stool examination and upper gastrointestinal endoscopy were done for each patient on the first and last day of the clinical trial.

Assessment

Subjective and objective Parameters – were used for the assessment of treatment. The objective parameters were Hb%, stool examination and upper gastrointestinal endoscopy. Assessment was made by grading as 0, 1, 2, and 3 on the basis of severity and duration of symptoms and favorable shift to left.

Evaluation of response

In view of the changes in the clinical features, the grading was done as follows:
- Complete cure 100%: Free from chief complaint [*avipaka* (indigestion), *hrit-kanthadaha* (heart burn), *tikta-amlaudgara* (acid eructation), *utklesa* (nausea), *vamana* (vomiting), *udarasula* (abdominal pain), *adhmana* (flatulence), *klama* (tiredness) and *aruchi* (anorexia)].
- Maximum improvement: From 75 to <100% improvement of the clinical features.
- Moderate improvement: From 50 to <75% improvement of the clinical features.
- Mild improvement: From 25 to <50% improvement of the clinical features.
- No improvement: <25% or no improvement in both subjective and objective parameters.

Observation and Results

It was observed from age wise distribution of patients that those of age within 20–29 years were more (56.66%) affected [Table 2].

Majority of the enrolled patients were males (70%) and the females formed 30% [Table 3].

Maximum number of patients were found to have up to primary education (50%), followed by those with secondary education (26.66%) and +2 level or above (23.33%) [Table 4].

The socioeconomic status of the enrolled patients revealed the maximum percentage of them to be present in poor-income group (70%) as compared to the number in middle-income group (23.33%) and high-income group (6.66%) [Table 5].

Based on the occupation, it is found that the prevalence of disease is more (43.33%) in the labor class followed by businessmen (20%), office workers and housewives (13% each) and students (10%) [Table 6].

Classification of patients according to *ahara* (dietary factor) showed that *amlarasadhikya ahara* (86.66%) consuming patients were the maximum affected, followed by *vidahi* (63.33), and

Table 1: Physico-chemical analysis of *Chincha kshara* and *Kadali kshara*

Item tested	Chincha kshara	Kadali kshara
pH of 10% solids	11.2	10.7
Specific gravity g/ml	2.29	1.824
Alkalinity/ml	24.50	8.25
Elements	%	%
Na_2O	7.43	6.72
Al_2O_3	0.14	0.09
P_2O_5	0.18	0.15
SO_3	4.51	11.61
K_2O	54.88	49.70
Fe_2O_2	0.61	0.70
CaO	1.14	0.63
Cl	10.97	19.53
As, Pb	Absent	Absent
Acid-insoluble silica (ash)	0.14	1.88
Total silica	0.90	2.36

abhisyandhibhojana(10%) *ahara*consuming patients were the least affected [Table 7].

Classification of patients according to *vihara* showed that they were habituated with *atapasevana* (60%) instead of *divaswapna* (20%) and *vegadharana* (20%) [Table 8].

Table 9 shows that more than 60% patients were addicted to tea/coffee, followed by tobacco (23.33%) and alcohol (16.66%).

The distribution of patients according to their *prakriti* shows 53.33% belonging to *vatapittaja*, whereas 43.33% were of *vatakaphaja* and the remaining 3.33% were *pittakaphaja* [Table 10].

The classification of patients according to the *kostha* indicated that that 50% of the patients were in *mridukostha*, and among them 60% of cases had *mandagni* followed by 36.66% and 13.33% were of *madya* and *krura kostha* respectively [Table 11].

Symptoms like *hrit-kanthadaha*, *tikta-amlaudgara* were found 100% in each group of patients, whereas *avipaka* was found in 100%, 90% and 80% patients in group C, K, and P, respectively. A*ruchi* and *klama* were found in 90% patients in group C, but they were present in 80% patients in the placebo group, and in 90% and 70% patients, respectively, in group K.

The symptoms of *utklesa*, *udarasula* and *Adhamana* were found within 60–80% of cases in the different groups. In upper gastrointestinal endoscopy, 90% patients were affected in groups C and P, whereas 80% patients were affected in group K [Table 12].

After assessment, it was found that in group C, 04(40%) patients were cured and 04(40%) patients showed maximum improvement, whereas in group K, 03(30%) and 05(50%) patients were in the stage of cure and maximum improvement, respectively. One patient (10%) each was in mild and moderate improvement stages in group C and K. But in the placebo group, 08 (80%) patients did not responded to the clinical trial and mild and moderate improvement was seen only in one patient each [Table 13].

Table 2: The distribution of patients according to age

Age in years	Group C	Group K	Group P	Total	Percentage
20–29	06	04	07	17	55.66
30–39	03	04	03	10	33.33
40 and above	01	02	00	03	10.00
Total	10	10	10	30	

Table 3: The distribution of patients according to sex

Sex	Group C	Group K	Group P	Total	Percentage
Male	08	06	07	21	70
Female	02	04	03	09	30

Table 4: The distribution of patients according to education

Education	Group C	Group K	Group P	Total	Percentage
Up to primary education	04	05	06	15	50
Up to secondary education	03	03	02	08	26.66
+2 level or above	03	02	02	07	23.33

Table 5: The distribution of patients according to socioeconomic status

Socioeconomic status	Group C	Group K	Group P	Total	Percentage
Poor income (<₹ 5000/month)	06	07	08	21	70
Middle income (₹ 5000–10,000/month)	03	03	01	07	23.33
High income (>₹10,000/month)	01	00	01	02	6.66

Table 6: The distribution of patients according to occupation

Occupation	Group C	Group K	Group P	Total	Percentage
Students	02	00	01	03	10
Businessmen	03	02	01	06	20
Office workers	01	01	02	04	13
Housewives	01	01	02	04	13
Labor	03	06	04	13	43.33

Table 7: The distribution of patients according to *ahara* (dietary factor)

Type of ahara	Group C	Group K	Group P	Total	Percentage
Pitta vardhaka	10	10	10	30	100
Viruddha	03	02	01	06	20
Vidahi	08	06	05	19	63.33
Amlarasaadhikya	09	08	09	26	86.66
Pistasana	04	03	02	09	36
Atibhojana	02	01	01	04	13.33
Abhisyandhibhojana	01	01	01	03	10

Statistical analysis showed that both the drugs *chincha* and *kadalikshara* reduced the symptoms of *avipaka*(indigestion), *hrit-kanthadaha* (heart burn), *tikta-amlaudgara* (acid eructation), *utklesa* (nausea), *adhmana* (flatulence), *klama* (tiredness) and *aruchi* (anorexia) significantly with $P<0.001$, whereas in placebo group, it was not significant ($P>0.05$). Improvement of the symptoms like *udarasula* (abdominal pain) was also found to be significant with both trial drugs ($P<0.01$), but no improvement was found in the placebo group. Hb in each group was increased, but the increase was not satisfactory. The endoscopy revealed that degree of gastritis was reduced in group C ($P<0.05$) and group K ($P<0.05$), whereas unsatisfactory result ($P>0.05$) was obtained in the placebo group [Table 14].

Discussion

The *kshara* preparations have been used since the time of Charaka[16] and Sushruta[3] in diseases related to gastrointestinal system such as *amlapitta*, *gluma*, *sula*, etc. It is an applied fact that *kshara* gets neutralized in combination with *amla*. Five *rasas* are present in *kshara* except *amla*. *Lavana rasa*, being *anurasa*, is converted to *madhura* when mixed with *amla*. So, the *teekshna guna* of *lavana rasa* present in *kshara* is neutralized due to its combination with *amla* as the water extinguishes the fire.[17]

Maximum patients enrolled in the clinical study were in the age group of 20–29 years (55.66%) and among them, males formed 70%. Maximum number of patients had up to primary education (50%) and were in the poor-income group (70%) and labor class(43.33%).

Table 8: The distribution of patients according to *vihara*

Vihara	Group C	Group K	Group P	Total	Percentage
Divaswopna	02	02	02	06	20
Vegadharana	01	02	03	06	20
Atapasevana	07	06	05	18	60

Table 9: The distribution of patients according to addiction

Addiction	Group C	Group K	Group P	Total	Percentage
Alcohol	02	01	02	05	16.66
Tea/coffee	04	08	06	18	60
Tobacco	04	01	02	07	23.33

Table 10: The distribution of patients according to *prakriti*

Prakriti	Group C	Group K	Group P	Total	Percentage
Vatapittaj	05	07	04	16	53.33
Pittakaphaj	01	00	00	01	3.33
Kaphavataj	04	03	06	13	43.33

Table 11: The distribution of patients according to *kostha*

Kostha	Group C	Group K	Group P	Total	Percentage
Mridu	06	05	04	15	50
Madya	03	04	04	11	36.66
Krura	01	01	02	04	13.33

Table 12: The incidence of clinical features ($n=10$ in each group)

Clinical features	Group C		Group K		Group P	
	No. of patients	Percentage	No. of patients	Percentage	No. of patients	Percentage
Avipaka	10	100	09	90	8	80
Hrit-kanthadaha	10	100	10	100	10	100
Tikta-amlaudgara	10	100	10	100	10	100
Utklesa	08	80	07	70	07	70
Udarasula	06	60	06	60	06	60
Adhmana	07	70	08	80	07	70
Klama	09	90	07	70	08	80
Aruchi	09	90	09	90	08	80
Gastritis	09	90	08	80	09	90

Table 13: The clinical assessment of results of different groups ($n=10$ in each group)

Clinical assessment	Group C		Group K		Group P	
	No. of patients	Percentage	No. of patients	Percentage	No. of patients	Percentage
Cure	04	40	03	30	00	00
Maximum improvement	04	40	05	50	00	00
Moderate improvement	01	10	01	10	01	10
Mild improvement	01	10	01	10	01	10
Unsatisfactory	00	00	00	00	08	80
Total	10	100	10	100	10	100

Table 14: The effectiveness of clinical trial drugs on symptoms (*n*=10 in each group)

Clinical symptoms	Group C				Group K				Group P			
	BT	AT	t	P	BT	AT	t	P	BT	AT	t	P
	Mean±SD	Mean±SD			Mean±SD	Mean±SD			Mean±SD	Mean±SD		
Avipaka	2.5 ± 0.88	0.25 ± 0.46	7.69	<0.001	2.22 ± 0.63	0.33 ± 0.5	7.26	<0.001	2.5 ± 0.88	2.5 ± 0.88	1.53	>0.05
Hrit-kanthadaha	2.3 ± 0.82	0.2 ± 0.42	9.13	<0.001	2.2 ± 0.78	0.3 ± 0.48	10.61	<0.001	2. ± 0.81	1.8 ± 0.89	1.50	>0.05
Tikta-amlaudgara	2.3 ± 0.82	0.2 ± 0.42	9.17	<0.001	2.0 ± 0.81	0.2 ± 0.42	9.00	<0.001	2.1 ± 0.87	1.9 ± 0.74	1.50	>0.05
Utklesa	1.62 ± 0.74	0.12 ± 0.35	8.02	<0.001	1.71 ± 0.75	0.14 ± 0.37	7.27	<0.001	1.42 ± 0.53	1.28 ± 0.75	1.00	>0.05
Udarasula	1.33 ± 0.51	0.0 ± 0.0	6.33	<0.01	1.66 ± 0.81	0.16 ± 0.41	6.72	<0.01	1.33 ± 0.51	1.33 ± 0.51	-	-
Adhmana	1.85 ± 0.89	0.14 ± 0.37	6.01	<0.001	1.75 ± 0.88	0.12 ± 0.35	6.17	<0.001	1.28 ± 0.48	1.28 ± 0.48	-	-
Klama	1.33 ± 0.5	0.0 ± 0.0	6.03	<0.001	1.28 ± 0.48	0.0 ± 0.0	6.98	<0.001	1.25 ± 0.46	1.0 ± 0.75	1.5	>0.05
Aruchi	1.77 ± 0.83	0.0 ± 0.0	6.41	<0.001	1.88 ± 0.71	0.0 ± 0.0	7.26	<0.001	1.5 ± 0.53	1.39 ± 0.74	1.0	>0.05
Hemoglobin (gm%)	2.6 ± 0.63	2.1 ± 0.83	1.96	>0.05	2.74 ± 0.90	2.23 ± 0.19	1.87	>0.05	2.69 ± 0.78	2.31 ± 0.84	1.78	>0.05
Gastritis	2.1 ± 0.82	1.14 ± 0.85	2.28	<0.05	2.48 ± 0.54	1.64 ± 0.19	2.30	<0.05	2.51 ± 0.49	2.18 ± 0.83	1.18	>0.05

During the assessment of clinical symptoms, it is found that patients were more exposed to *atapasevana* (60%) and their intake habits were *pittavardhaka* (100%), *amlarasadhikya* (86.66%) and *vidahiannaahara* (63.83%). They were suffering from *agnimandya*due to *mridukostha* (50%) or were addicted to tea and coffee (60%).

Among the main symptoms of *amlapitta*, *hrit-kanthadaha* and *tikta-amlaudgara* were found in all the patients (100%) of each group and other symptoms like *avipaka*, *utklesha*, *aruchi*, *udarasula* and *adhmana* were also seen in 60–90% patients *Chincha kshara* and *Kadali kshara* cured 04(40%) and 03(30%) patients, respectively, and maximum improvement was seen in 04(40%) and 05(50%) patients, respectively. Unsatisfactory (80%) result was obtained with the placebo drug.

Statistical analysis inferred that *avipaka* (indigestion), *hrit-kanthadaha* (heart burn), *tikta-amlaudgara* (acid eructation), *utklesa* (nausea), *adhmana* (flatulence), *klama* (tiredness) and *aruchi* (anorexia) were statistically reduced (*P*<0.001), but reduction in *udarasula* was less statistically significant as compared to the aforesaid symptoms [Table 14]. No improvement was detected in the placebo group patients (*P*>0.05). It is also found that the signs of gastritis was reduced satisfactorily in group C (*P*<0.05) and group K (*P*<0.05), but was unsatisfactory in the placebo group (*P*>0.05).

This clinical study reveals that both *ksharas* gave satisfactory relief and *chincha kshara* gave relatively better result than *kadalikshara*. No advers effects of *ksharas* were seen during the clinical study period.

Conclusion

In nutshell, on the basis of aforesaid parameters, it can be said that *Chincha kshara* was more effective than *Kadali kshara* due to its more alkaline nature. However, it is a humble attempt to give a scientific base to classical claim of *kshara* application with the limited facilities available so far. This can further be expanded and confirmed by suitable experimental study on the animals and taking a large sample to make it more scientific and effective.

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हिन्दी सारांश

अम्लपित्त के रोगियों में चिन्चाक्षार एवं कदली क्षार औषधियों के प्रयोग का तुलनात्मक अध्ययन

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अम्लपित्त से पीड़ित ३० रोगियों, जिनकी उम्र २०–३५ वर्ष के बीच एवं मुख्य लक्षण अविपाक, हृदकण्ठ दाह, तिक्तअम्लोद्गार, उत्क्लेश, उदरशूल और आध्मान थे, उनको गोपबन्धु आयुर्वेद महाविद्यालय, पुरी से नैदानिक अध्ययन के लिए चुना गया। इन्हें समान तीन वर्गों में विभक्त करके चिन्चाक्षार, कदलीक्षार और कन्ट्रोल ग्रुप (गेहूँ का चूर्ण) पर रखा गया। रोगियों को चिन्चाक्षार, कदलीक्षार 500 mg मात्रा में दिन में ३ बार नियमित रुप से ३० दिन तक प्रयोग कराया गया। इन रोगियों का Subjective एवं Objective रुप से परीक्षण किया गया। चिन्चाक्षार द्वारा चिकित्स्य रोगियों में ४ रोगी और कदलीक्षार चिकित्स्य रोगियों में केवल ३ रोगियों में उत्तम लाभ परिलक्षित हुआ। चिन्चाक्षार चिकित्सा वर्ग में अधिक अच्छा परिणाम प्राप्त हुआ। परन्तु कन्ट्रोल ग्रुप के रोगियों पर कोई अच्छा प्रभाव देखने को नहीं मिला। इस तुलनात्मक अध्ययन में किसी रोगी पर कोई विपरीत प्रभाव नहीं दिखाई दिया।