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-kanthhadaha, tikta-amlodgara, utklesa, udarasula, adhimana 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,[1] seta and shukla. They possess Deepana,[4] pachana, chhedana, pacify tridosha, clears srotas and destroy the krimis.[7] Taste of kshara is pancharasasing be lavana as anurasa and devoid of amlarasasa.[8] By asserting the real state of dosas, an efficient physician with kshara expertise can well treat the patients suffering from amlapitta,[9] grahan, sula, gubra,[11] maddagni, 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 kshara 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
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), amasayavarna (stomach ulcer), grahamivrana (duodenal ulcer), garbhavasta (pregnancy), lactation, cancer in stomach, pittasayaasamari (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 Chinchakshara (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.[2] When amla is predominant,[3] 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 Chinchka (tamarind)[10] and Kadali (plantain)[11] are mentioned under phalavarga in classical texts, and the kshara prepared[12] out of the tamarind bark and leaves of plantain is advocated in the treatment of gulma, ajeerna, mandagni, amlapitta, adhmana, etc.[13] The physico-chemical analysis of chinchka 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.

Table 1: Physico-chemical analysis of Chinchka kshara and Kadali kshara

| Item tested | Chinchka 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 | % | % |
| Na₂O | 7.43 | 6.72 |
| Al₂O₃ | 0.14 | 0.09 |
| P₂O₅ | 0.18 | 0.15 |
| SO₃ | 4.51 | 11.61 |
| K₂O | 54.88 | 49.70 |
| Fe₂O₃ | 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 |

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 the business class (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...
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 prakriti shows that 53.33% belonged 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 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. Aruchi 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, udrasula 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].
Statistical analysis showed that both the drugs chinchaksha and kadali kshara 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.

### Discussion

The kshara preparations have been used since the time of Charaka[1] and Sushruta[2] 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      | 06      | 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       |
| Kaphavatay | 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 |
|-------------------|---------|---------|---------|-----------------|------------|
| Avipaka           | 10      | 09      | 08      | 100             | 80         |
| Hrit-kanthadaha   | 10      | 10      | 10      | 100             | 100        |
| Tikta-amlaudgara  | 10      | 10      | 10      | 100             | 100        |
| Utklesa           | 08      | 07      | 08      | 80              | 70         |
| Udarasula         | 06      | 06      | 06      | 60              | 60         |
| Adhmana           | 07      | 08      | 07      | 70              | 70         |
| Klama             | 09      | 07      | 08      | 90              | 80         |
| Aruchi            | 09      | 09      | 08      | 90              | 80         |
| Gastritis         | 09      | 08      | 09      | 90              | 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 |
|---------------------|---------|---------|---------|-----------------|------------|
| Cure                | 04      | 03      | 00      | 40              | 00         |
| Maximum improvement | 04      | 05      | 00      | 40              | 00         |
| Moderate improvement| 01      | 01      | 01      | 10              | 10         |
| Mild improvement    | 01      | 01      | 01      | 10              | 10         |
| Unsatisfactory      | 00      | 00      | 08      | 00              | 08         |
| Total               | 10      | 10      | 10      | 100             | 100        |
Table 14: The effectiveness of clinical trial drugs on symptoms (n=10 in each group)

| Clinical symptoms | Group C Mean±SD | Group P Mean±SD | t   | P   | Group K Mean±SD | t   | P   |
|-------------------|-----------------|-----------------|------|-----|-----------------|------|-----|
| Avipaka           | 2.5 ± 0.88      | 2.0 ± 0.84      | 0.72 | >0.05| 2.5 ± 0.88      | 0.72 | >0.05|
| Hrit-kanthadaha   | 2.3 ± 0.82      | 2.0 ± 0.84      | 0.72 | >0.05| 2.3 ± 0.82      | 0.72 | >0.05|
| Tikta-amlaudgara  | 2.3 ± 0.82      | 2.0 ± 0.84      | 0.72 | >0.05| 2.3 ± 0.82      | 0.72 | >0.05|
| Utklesa           | 1.62 ± 0.74     | 1.39 ± 0.74     | 2.68 | <0.01| 1.62 ± 0.74     | 2.68 | <0.01|
| Udarasula         | 1.33 ± 0.51     | 1.0 ± 0.51      | 3.33 | <0.01| 1.33 ± 0.51     | 3.33 | <0.01|
| Adhmana           | 1.85 ± 0.89     | 1.64 ± 0.89     | 2.30 | <0.01| 1.85 ± 0.89     | 2.30 | <0.01|
| Klama             | 1.3 ± 0.50      | 1.0 ± 0.50      | 3.33 | <0.01| 1.3 ± 0.50      | 3.33 | <0.01|
| Aruchi            | 1.77 ± 0.83     | 1.5 ± 0.83      | 2.30 | <0.01| 1.77 ± 0.83     | 2.30 | <0.01|
| Hemoglobin (gm%)  | 2.6 ± 0.63      | 2.3 ± 0.63      | 0.63 | >0.05| 2.6 ± 0.63      | 0.63 | >0.05|
| Gastritis         | 2.1 ± 0.82      | 1.8 ± 0.82      | 2.30 | <0.01| 2.1 ± 0.82      | 2.30 | <0.01|

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 vidahamahathara (63.83%). They were suffering from agnimandya due to mridukotha (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 Chinchakshara and Kadali kshara cured 04(40%) and 05(50%) 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), utklesha (nausea), adhmana (flatulence), klama (tiredness) and aruchi (anorexia) were statistically reduced (P<0.01), 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 chinchakshara gave relatively better result than kadalikkshara. No adverse effects of ksharas were seen during the clinical study period.

Conclusion

In nutshell, on the basis of aforesaid parameters, it can be said that Chinchakshara 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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अम्लपित्त से पीड़ित 30 रोगियों, जिनकी उम्र 20–35 वर्ष के बीच एवं मुख्य लक्षण अविपाक, हुदकण्ठ दाह, तिकतम्बोद्वार, उत्तलास्वास्त्र और आध्यात्मिक विषयों के लिए चुना गया। इन समान तीन वर्गों में विभाजित करके चिकित्सकर, कदलीक्षार और कन्ट्रोल ग्रुप ( रोय्ड का चूर्ण) पर रखा गया। रोगियों को चिकित्सकर, कदलीक्षार 500 mg मात्रा में दिन में 3 बार नियमित रूप से 30 दिन तक प्रयोग कराया गया। इन रोगियों का Subjective एवं Objective रूप से परीक्षण किया गया। चिकित्सकर और कन्ट्रोल ग्रुप में 4 रोगी और कदलीक्षार ग्रुप में केवल 3 रोगियों में उत्तम लाभ परिलक्षित हुआ। चिकित्सकर 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।