RESEARCH ARTICLE

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF KHANDKUSHMANDAK AVLEHA AND SYRUP PATOLADI ON AMLAPITTA IN CHILDREN

[1,] *Dr. Shilpi Sharma and [2]Rakesh Sharma

Department of Kaumarbhritya, Babe k Ayurvedic College and Hospital Daudhar, (Moga) Punjab, India
Department of Kaumarbhritya Rajeev Gandhi Govt. P.G. Ayurvedic Medical College Paprola, Distt. Kangra, Himachal Pradesh, India

ABSTRACT

A drastic change in mankind has taken place mostly due to urbanization and industrialization. To cope-up with the speed of the modern era, one has to adopt junk food preparations, over-work and stressful duty schedule. Vitiation of *Agni* due to various causes leads to *Amlapitta.* Some of the common causes are - fasting, eating between meals, worry, hurry, spicy foods etc. These factors affect the *Pachakapitta* (digestive enzymes etc.) and as a result *Pachakapitta* vitiates. Thus the developed condition is called *Amlapitta.* A comparative clinical study was adopted in the clinical trial. 40 patients fulfilling the diagnostic and inclusion criteria were selected and randomly assigned into two groups i.e. group I and II. Without any dropout, the children in group I was treated with *Khandkushmandaka Avleha* and the children in group II were treated with *Syrup Patoladi* for 30 days. Result obtained after the clinical trial was analysed statistically and all the observation were subjected to creative discussion.

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INTRODUCTION

Ayurveda is the traditional science of medicine practiced in India since centuries. It is the science for long life which cures not only the disease but also teaches how to live healthy and prevents the diseases.

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Amlapitta is the disease of *Annavaha Srotas* but it has not been independently described as a separate disease in *Brihtrai*. Scattered references of *Amlapitta* are available in *Charaka Samhita* but the detailed explanation available in *Kashyapa Samhita[2],* for the first time as *Shuktaka* wherein *Doshika* classification of the disease is mentioned. *Madhava Nidana* describe classification on *Gati* basis[3] and was first one to describe it as *Amlapitta.* This is basically a disease of gastro–intestinal tract, due to abnormal secretions of gastric juices. On the basis of symptoms, pathophysiology of the disease, it may be Acid Peptic Disorder specially Non-ulcer dyspepsia in the present scenario.

Aims and objectives

- To analyse the prevalence of *Amlapitta* in children.
- To study the efficacy of *Khandkushmandaka Avleha* and Syrup *Patoladi* in management of *Amlapitta.*
- To compare the efficacy of both the drugs with each other.

- To evaluate the safety of both the drugs in children.

MATERIALS AND METHODS

- Screening
- Enrollment

Screening: The patients attending the departmental OPD with symptoms and signs of *Amlapitta* were included in the study.

Enrollment

Selection of patients: Patients were selected from the OPD/IPD of *Kaumarbhritya- Bal Roga* department of R.G.G.P.G. Ayu. Hospital Paprola, Kangra (H.P.) randomly fulfilling the criteria of diagnosis.

Inclusion criteria

- Patient between 6 to 16 years of age.
- Patients having clinical features of *Amlapitta.*
- Patients/ parents of the patient willing to participate in the trial.

Exclusion criteria

- Patient with any systemic illness.
- Patient having *Parinamashoola* or *Annadravashoola*.

- Patient having any malignancy and genetic disorder.
- Patient having clinical features of cholilithiasis and cholecystitis.
- H/O haematemesis, malena and gastric surgery.
- Children below or above the mentioned age group.
- Patients/parents of the patient not willing to participate in the trial.

Discontinuation criteria

- Non compliance of treatment regimen.
- Patient /parents want to withdraw from trial.
- Adverse drug reaction confirm with causality assessment may be withdrawn.
- If the condition of patients deteriorates during trial.

Trial drug: The drugs were prepared in the *Charak Ayurveda* Pharmacy, Paprolaunder the supervision of Deptt. of *Rasa-Shastra* and *Bhaishajya-kalpnana*.

Assessment criteria: Assessment of effect of therapy was done on the basis of various subjective and objective parameters before and after treatment.

Subjective Assessment: Scoring system was adopted for assessment of various subjective criteria and grades from zero to three, according to the severity. The grading of various clinical features is as follows:

Clinical featuresGrading

Hritkanthadaha

- No *Daha* 0
- *Daha* of mild degree 1
- *Daha* of moderate degree relieved by cold Milk, drinks, antacids, food and vomiting. 2
- *Daha* of severe degree not relieved by cold milk, drinks, antacids, food and vomiting. 3

Amla-Udgara

- No *Amla-Udgar* at all 0
- Occasional *Amla-Udgar* during day 1
- Continuous mild *Amla-Udgar* 2
- Continuous severe and excessive *Amla-Udgar* 3

Utklesha

- Absent 0
- Occasional desire to vomit 1
- Frequent desire to vomit 2
- Continuous desire to vomit hampering food intake 3

Avipaka

- Normal digestion 0
- Indigestion once or twice a week 1
- Indigestion three to five times a week 2
- Indigestion after every meal 3

Vaman

- No vomiting0
- Feels sense of nausea and vomits occasionally 1

- Frequency of vomiting between four to six per week 2 and increases when pain is aggravated
- Frequency of vomiting daily after every meal 3

Aruchi

- Normal desire for food 0
- Eating timely without much desire 1
- Desire for food only after long interval 2
- No desire for food at all 3

UdarAdhman

- Absent 0
- Occasional feeling of flatulence or gaseous in abdomen 1
- Moderate complaint or discomfort 2
- Continuous flatulence in abdomen 3

Klama

- No complaint 0
- Mild *Klama* but patient is able to do routine work 1
- Continuous *Klama* which hampers routine work 2
- Continuous *Klama* and patient is unable of doing any Work 3

Vidbheda

- Normal 0
- Motion three to four times a day 1
- Motion five to six times a day 2
- Motion > 6 times a day 3

GuruKoshtha

- Absent 0
- Occasional, heaviness in abdomen 1
- Moderate complaint of discomfort 2
- Continuous heaviness and discomfort in abdomen 3

Angasada

- No *Angasada* 0
- Occasional *Angasada* but patient is able to do routine work 1
- Continuous *Angasada* which hampers routine work 2
- Continuous *Angasada,* patient is unable of doing any work 3

Shoola

- No pain 0
- Mild pain of low intensity, does not hamper normal routinework 1
- Moderate pain, hampers the daily routine work 2
- Severe pain causing interruption making patient unable to do any work 3

Objective criteria

- C B C
- L F T (S. billirubin i.e. direct and indirect, SGOT, SGPT)
- FBS

- Urine examination
- USG hepato-biliary system (if required)

Duration of the intervention: 30 Days
Mode of intervention: orally

Drug dosage:

Khandkusmandaka Avleha: 250-500 mg/kg body wt. in two divided doses

Syrup *Patoladi:* 1.0-1.6 ml/kg/day in two divided doses

Follow up: 2 follow up (one after 2 weeks and one after completion of trial.)

Statistical analysis

The obtained data was analyzed statistically and expressed in terms of mean score before treatment (BT), after treatment (AT), difference of mean (BT – AT), standard deviation (SD) and standard error (SE). Overall percentage improvement of each patient was calculated by the following formula:

$$\frac{\text{Total BT} - \text{Total AT}}{\text{Total BT}} \times 100$$

Student paired 't' test was applied at p >0.05, p<0.05, p<0.01, and p<0.001, to observe significance of results obtained after treatment. The results were considered significant or insignificant depending upon the value of p.

- Extremely significant - p<0.0001
- Highly significant-p<0.001
- Significant-p<0.05-0.01
- Insignificant-p >0.05

Total effect of therapy

The assessment hus obtained from individual patients were categorized according to the following grades

- Markedly improved -76-99% improvement in clinical features
- Moderately improved-51-75 % improvement in clinical features
- Mildly improved-26-50% improvement in clinical features
- No improvement-Below 25% improvement in clinical features

RESULTS

Effect of therapy on subjective parameters

1. *Hritkanthadaha* (Retrosternal burning): It was present in 62.5% patients (65% patients in group I and 60% in group II). In *Amlapitta* there is burning sensation in retrosternal area, sometimes it may present to whole body. It depend upon extent of *Pitta*. If *Pittadusti* is present only in *koshta*, then there is burning sensation in retrosternal area. But in the later stages, it affects *Sakha* as well, which results in the burning sensation of the other part of body also. In group-I 73.66% and in group-II 66.68% relief was found. Results were statistically highly significant for both groups I and II (p<0.001). Intergroup comparison shows that the effect of therapy on *Hritkanthadaha* was better in group- I patients, with 6.98% more relief than group-II. This difference was statistically insignificant at p>0.05.

2. *Amlodgar* (Sour and bitter Belching): It was recorded in 47.5% (50% patients in group I and 45% in group II). Normal *rasa* of *Pitta* is *Katu*, but when it become *vidhgdha, katu rasa* is changed into *Amla. Amla* and *dravaguna* of *pitta* leads to *Amlodgara* and *Utklesh.* In group-I 76.92% and in group-II 36.33% relief was observed. Results were statistically highly significant (p<0.001) for group I and significant for group II (p<0.05). Inter group comparison shows that effect of therapy on *Amlodgar* was 40.59% more in group-I patients. However, statistically the difference was insignificant at p>0.05.

3. Utklesha (Nausea): 47.5% patients (55% patients in group I and 45% in group II) were having *Utklesha.* After treatment 66.64% relief in group-I and 25% relief in group-II was assessed. Results were significant statistically (p<0.01) for group-I and insignificant for group-II (p >0.05). Intergroup comparison shows that the effect of therapy on *Utklesha* was 41.64% more in group-I patients. However, statistically the difference was insignificant at p>0.05.

4. *Avipaka* (Indigestion): 62.5% patients. (65% in group I and 60% in group II) were reported having *Agnimandhya* which leads to *Avipaka*. After food intake, there is a feeling that the food is not digested which causes discomfort to the person. 55.52% relief in Group I and in Group-II 26.34% relief was assessed. Results were statistically highly significant for group-I and significant for group II (p<0.05). Intergroup comparison shows that the effect of therapy on *Avipaka* was better in group-I patients, with 29.34% more relief than group-II. However, statistically the difference was insignificant at p>0.05.

5. Vaman (Vomiting): Vaman was present in 62.5% patients. (60% in both group I and 65% in group II). In this symptom 26.34% relief was observed in group-I and 36.79% relief was observed in group-II. This data suggests insignificant results (p >0.05) for group I and statistically significant for group II (p<0.01). Intergroup comparison shows that the effect of therapy on *Vaman* was better in group-II patients, with 10.45% more relief than group-I. This difference was statistically insignificant at p>0.05.

6. *Aruchi* (Loss of appetite): It was reported in 85% patients (85% in both group I and group II). Due to *Manasikabhavas* and vitiated *Vatadidoshas*, there is loss of interest to food. This indicates the somatic as well as the psychic components are responsible for the *Aruchi.* 57.68% relief was observed in group-I and 38.45% relief was observed in group-II. This data suggests highly significant results in group-I (p<0.001) and significant in group-II (p<0.01) statistically. Intergroup comparison shows that the effect of therapy on *Aruchi* was better in group-I patients, with 19.23% more relief than group-II. This difference was statistically insignificant at p>0.05.

7.Udaraadhaman (Flatulence): 87.5% patients (90% in group I and 85% in group II) were having *Udaradhmana*. It is due to excessive production of *Vata.* Due to *Avipaka,* there is

Shuktatapaka of *Anna* i.e. fermentation which leads to formation of excessive *Vata*. This symptom showed 57.68% relief in group-I and 38.45% relief in group-II. Results were highly significant in group-I statistically and significant for group-II(p<0.01). Intergroup comparison shows that the effect of therapy on *Udaraadhaman* was 19.23% more in group-I, that is statistically insignificant at p>0.05.

8. *Klama* (Mental fatigue): It was found in 32.5% patients (35% in both group I and 30% in group II). *Klama* means fatigue, without any workout. One will have a decreased energy level as well as disinterest in their routine activities. This occurs due to the *Amadosha* present in the body, which affects all the functions and also there is decreased in BMR. These all leads to *klama*, and *Angsada*. In this symptom 37.53% relief was observed in group-I and 50.03% relief was observed in group-II. The result was statistically insignificant for group-I and group- II (p<0.05). Inter group comparison shows that the effect of therapy on *Klama* was better in group-II patients, with 12.5% more relief than group-I however, the difference was statistically insignificant at p>0.05.

9. *Vidbheda* (Loosemotions): *Vidbheda*was reported in 62.5% patients (65% in group I and60% in group II). There is *Atipravritti*or *Apravrithi* of *dosha* in *Ajeerna*. *Vatadusti* and *Agnimandya* are the main responsible factors for developing *Vidbheda*. 66.63% relief in group –I and 22.65% relief was observed in group-II. The result was statistically highly significant for group-I (p<0.001) and insignificant for group-II (p>0.05). Inter group comparison shows that the effect of therapy on *Vidbheda* was better in group-I patients with 43.98% relief than group-II. However, the difference was statistically insignificant at p>0.05.

10.*Gurukoshtha* (Heaviness in abdomen): 62.5% patients (65% in group I and 60% in group II) were suffering from *Mandagni* and vitiation of the *dosha* peculiarly, *Ama* or *Kapha* are responsible for producing this symptom, *Gurukoshtata*. There is also delayed gastric emptying. In this symptom 31.27% relief was assessed in group-I and 26.34% relief was assessed in group-II. The result was statistically significant for both groups (p<0.05). Inter group comparison shows that the effect of therapy on *Guru koshtha* was better in group-I patients with 4.93 relief than group-II. However, the difference was statistically insignificant at p>0.05.
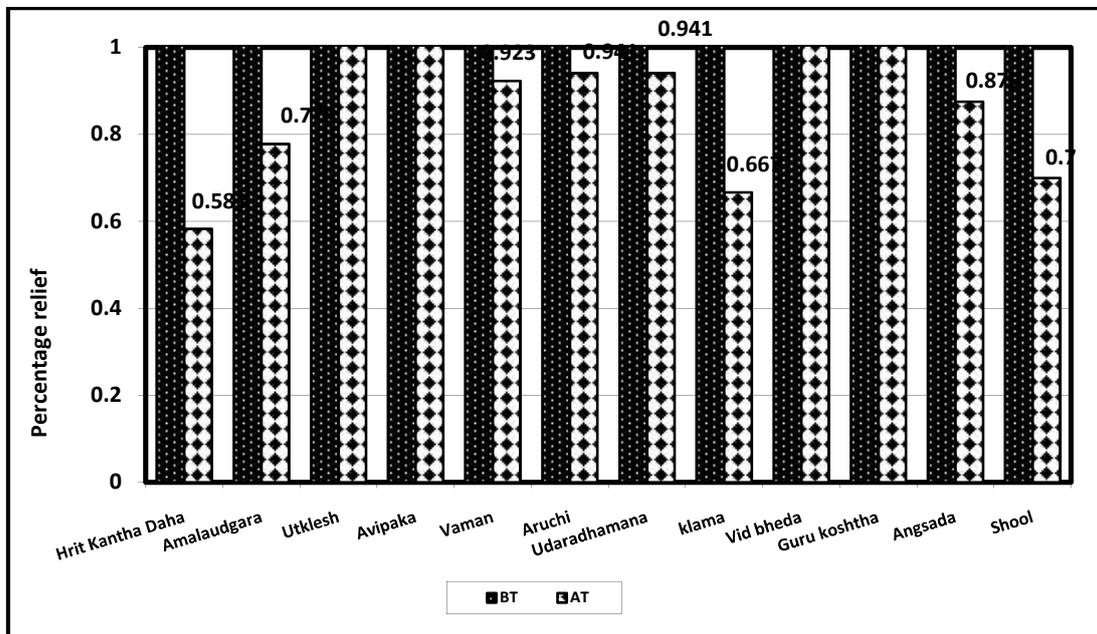
11.*Angsada* (Exhausation): It was present in 37.5% patients (35% in group- I and 40% in group-II). 49.95% relief was found in group-I and 41.66% relief was found in group-II. The result was statistically insignificant for group I (p>0.05) and statistically significant for group II (p<0.01). Inter group comparison shows that the effect of therapy on *Angsada* was better in group-I patients with 8.29% relief than group-II. However, the difference was statistically insignificant at p>0.05.

12. *Shoola* (Pain): *Shoola* was found in 100% patients (100% in both group- I and in group-II). In group-I 57.57% relief was observed and 53.33% relief was observed in group-II for this symptom. The result was statistically highly significant for both group-I and group-II (p>0.001). Inter group comparison shows that the effect of therapy on a *Shoola* was better in group-I patients with 4.24% relief than group-II However, the difference was statistically insignificant at p>0.05.
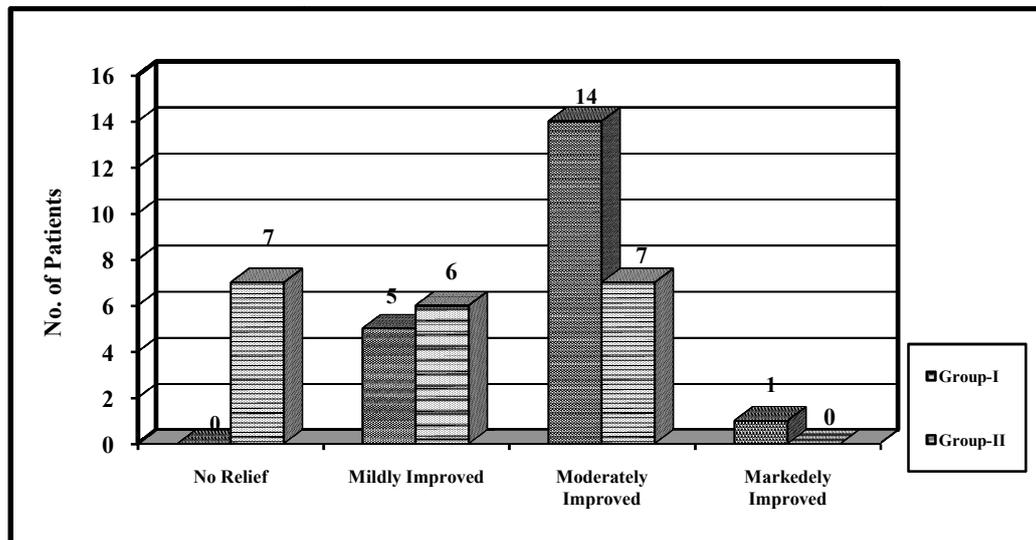
B). Effect of therapy on objective parameters: Effect of therapy on objective parameters were within normal limits in both the groups and the difference in the mean score values of blood investigations before and after treatment was statistically insignificant in both the groups(p >0.05). Routine and microscopic examination of urine showed no effect before and after the treatment.

Graphical presentation of intergroup comparison on subjective criteria: The effect of therapy on objective parameters were within normal limits in both the groups and the difference in the mean score values of blood investigations before and after treatment was statistically insignificant in both the groups(p >0.05). Routine and microscopic examination of urine shows no effect before and after the treatment.

Overall effect of therapy: In 20 patients of group one, 5 patients were mildly improved, 14 patients moderately improved and 1 patient was markedly improved. In group two, 6 patients were mildly improved, 7 patients were moderately improved and 7 patients showed no relief among 20 patients, Overall effect of therapy shows that, 2.5% patients showed marked improvement, 52.5% patients were moderately improved, and 27.5% patients showed mild improvement and 17.5 % patients showed no improvement.

Category of improvement	Gr.- I		Gr.- II		Total	
	No. of pts.	% age	No. of pts.	% age	No. of pts.	% age
No relief	0	0%	7	35%	7	17.5%
Mildly improved	5	25%	6	30%	11	27.5%
Moderately improved	14	70%	7	35%	21	52.5%
Markedly improved	1	5%	0	0%	1	2.5%

DISCUSSION

The pathogenesis of *Amlapitta* involves three important factors i.e. *Agnimandya, Ama* and *Annavaha Srotodushti*. Along with this, the vitiation of *Pitta* specially *Pachaka Pitta* gives rise to *Amlapitta*. The gastric glands produces acids, which help break down food during digestion. But if there is more production of acid, it leads to hyperacidity. There are varieties of reasons which cause excess acid production. All these above factors result in vitiation of '*Pitta Dosha*' which tries to find its way out of the body either through oral or rectal pathway and along with it exhibits symptoms of *Amlapitta*. The dietary interventions can be of much benefit in the disease as the majority of causes are dietary. *Ayurveda* has provided a simple and cost-effective treatment for disease. Main line of treatment is to correct *Ama* formation and *Agnimandya*. *Amashodhana* is done by *MriduVaman, Mridu Virechana, Anuvasana and Niruhan*. In the persons who are already weak, *Deepana* and *Ama Paachan* with the relevant herbs and medicines are to be employed. All contents of *Khandkushmandaka Avleha* having *Madhura Rasa, SheetaVeerya, Madhura Vipaka*. These are predominately *Vata-Pitta Shamaka and* help in relieving *Hrita-Kanthadaha, Amlodgara, Tiktodgara* etc. *Tikta-Kashaya rasa* of *Amalaki* also helps in relieving *Amla-Tiktodgara*. This is also rich in gastro-protective tannins. Milk strengthens the muscle of esophagus to help to prevent the acid reflux. It also prevents the build- up of excess acid in stomach. On the basis of soothing effect of *Madhura Vipaka*, it can be said that this may help in production of healthy tissue in inflammatory condition. Ingredients of "Syrup *Patoladi*" have *Madhura, Tikta, Katu and Kashaya Rasa. Madhura Rasa* is having *Sheeta,* and *Guru* properties. These properties antagonize the *Ushna, Tikshna* and *Laghugunas* of *Pitta Dosha. Madhura Rasa* is *PittaVataShamaka*[5]*.Madhura Rasa* is also having *Manaprasadan Guna*[6]*and* due to this it also counters the *ManshikhaBhava. Tikta* and *Kashaya Rasa* have *Ruksha, Sheeta*properties[7]. Due to these properties, these *Rasas* pacify the *Sanigdha, Ushna,* and *Tikshna Guna* of *Pitta*. Due to *Agnimandya* at *Jatharagni* level,*Annarasa* becomes *Vidagdha*

and there is *Ama* formation resulting in *Rasa Dhatu Dusti*. Thus *Deepana*and *Aamapachana Karma* is required. *Tikta Rasa* is having properties like *Deepana, Pachana* and *Rochana* 8. *Tikta rasa* decrease the *Dravata of Pitta Dosha* by *Shoshan* of *Jala* dominant substance so it benefits in pacifying symptoms of *Amlapitta*.

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Katu rasa is also having *Deepana*, and *Pachana* properties which helps indigestion of *Ama*.

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Madhuravipaka of *Pippali* and *Sita* helps in relieving *Amla-Tiktodgara*. According to *Doshghanta*, maximum drugs are having *Pittashamakaguna. Patola* also helps in relieving *Aadhmana* through their *Anulomaka* property. All contents of these formulations balance the each other's drawback. The pharmacological properties of the individual drugs favor its effect in disease. Thus, all these properties help in resolving the*Samprapti chakra* of *Amlapitta* at various levels. That's why those drugs were selected in the trial which had mainly *Pittashamaka, kaphashamka* and also *Vatashamaka* properties along with *Deepana, Pachana, Rochana* action.

Conclusion

There is an involvement of all the three *Doshas*in *Amlapitta* but the vitiation of *Pitta Dosha* is of prime importance .In *Amlapitta, Mansika Bhava* also plays major role with *Sharirikabhava*, when these gets vitiated, they cause *Agnimandhya* which leads to *Annavisha* formation which ultimately give origin to disease *Amlapitta.* The outcome of clinical study was insignificant statistically on subjective as well as objective criteria in intergroup comparison. Although on comparison between two groups, *Khandkushmandaka Avleha* have shown more effect than Syrup *Patoladi*. Both the selected *drugs* showed better results with its *Pitta Shamaka*

and Deepana-Pachana properties. The positive point observed during the study that, there were no side effects seen during the trail, which is really a good sign to the patients and is of vital importance in view of the global acceptance of *Ayurveda*. As the saying goes "Prevention is better than cure" it is better to avoid all the causative factors of *Amlapitta* and thus lead to healthy life.

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