

# A clinical Study to Evaluate the Efficacy of Khandkushmandaka Avleha on Amlapitta in children

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## ABSTRACT:

Due to urbanization, a drastic change in mankind has taken place. One has to adopt junk food preparations, over-work and stressful duty schedule for adjustment in this Era. Vitiation of *Agni* due to various causes leads to *Amlapitta*. Moreover fasting, eating between meals, worry, hurry, spicy foods are also becoming a part of our life. These factors affect the *Pachaka pitta* and as a result *Pachaka pitta* vitiates. Thus the developed condition is called *Amlapitta*. A clinical study was adopted in the clinical trial. 20 patients fulfilling the diagnostic and inclusion criteria were selected. Without any dropout, the children were treated with *Khandkushmandaka Avleha* for 30 days. Result obtained after the clinical trial was analysed statistically and all the observation were subjected to creative discussion.

Keyword: *Agni*, *Amlapitta*, *Pachaka pitta*, *Khandkushmandaka Avleha*.

## INTRODUCTION:

Among the eight different branches of Ayurveda, Kaumarbhritya considered as the most important specialty according to *AcharyaKashyapa* , who cover each aspect of child health care<sup>1</sup>. W.H.O. defines health as “a state of complete physical, mental, social and spiritual wellbeing and not merely the absence of disease or infirmity.”Children are the pillars of society; it is the duty of every science to avert them from the diseases.

21<sup>st</sup> century the era of competition, life is full of stress having more speed and accuracy with prime demands. Today’s diet pattern, life styles and behavioral pattern are completely changed and are not suitable for the normal physiology of digestion of body. Now a day’s children are more attracted towards the junk food. Now children prefer comfortable living and avoid doing any kind of physical activity. They are aware about "WHAT TO EAT?" but least about "HOW TO EAT? The stress due to work, lack of exercise and faulty food habits in

children leads to disturbance of *Agni* or metabolism which leads to many disorders, *Amlapitta* is one of them.

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*Agni* and *Pitta* are the main factors responsible for digestion, due to their abnormality; food is not properly digested and produces the *Ama*, which is acidic in nature. Detailed explanation of *Amlapitta* is available in *Kashyapa Samhita*<sup>3</sup>, for the first time as *Shuktaka* wherein *Doshika* classification of the disease is mentioned. *Madhava Nidana* describe classification on *Gati* basis and was first one to describe it as *Amlapitta*<sup>4</sup>. 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:**

- i. To analyse the prevalence of *Amlapitta* in children.
- ii. To study the efficacy of *Khandkushmandaka Avleha* in management of *Amlapitta*.
- iii. To evaluate the safety of the drug in children.

#### **MATERIALS AND METHODS:**

- A. Screening
- B. Enrollment

##### **A. Screening:**

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

##### **B. Enrollment:**

##### **Selection of patients**

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

**Inclusion criteria:**

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

**Exclusion criteria:**

- i. Patient with any systemic illness.
- ii. Patient having *Parinamashoola* or *Annadravashoola*.
- iii. Patient having any malignancy and genetic disorder.
- iv. Patient having clinical features of cholelithiasis and cholecystitis.
- v. H/O haematemesis, melena and gastric surgery.
- vi. Children below or above the mentioned age group.
- vii. Patients/parents of the patient not willing to participate in the trial.

**Discontinuation criteria:**

- Non compliance of treatment regimen.
- Patient /parents want to withdrawl 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, Paprola* under the supervision of Deptt. of *Rasa-Shastra* and *Bhaishajya-kalpna*.

**Group 1-Khandkushmandaka Avleha**

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eUnkfXuukipsrloZa ;kon~Hkofrfif.Mre~AA<sup>5</sup>

**Method of preparation:**

- All ingredients in pharmacopial quantity were taken.
- Amalaki, were washed, cleaned and dried. They were powdered and passed through 180 µm IS (sieve number 85) to obtain fine powder.
- Fresh mature fruits of *Kushmandaka* were taken and removed skin and seeds of fruits followed by cutting the fruits into small pieces of 2.5cm to 5 cm. Added double quantity of water and heated to make *pishti*.

- Strained liquid was kept separately and boiled pieces of *kushmanda* were crushed in an endrunner mill to make a fine paste.
- *Go-Ghrita* was taken in a stainless steel vessel and heated till it became free from moisture and fried the *Kushmanda* paste in *Ghrita* till the mixture turned brown.
- Sita was added to strained liquid and heated maintaining the temperature between 80° and 90°C to make two thread sugar syrup.
- The fried paste was added to the syrup, heated with constant stirring. The mixture was examined for formation of bolus which did not disperse in water. Heating was stopped and allowed to cool.
- Fine powder of ingredients were mixed thoroughly to prepare a homogenous mixture and allowed to cool it to room temperature.
- It was stored in containers and packed in air-tight 500 gm jars to protect from light and moisture.

#### Assessment criteria:

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

#### A. 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 features	Grading
<b>1. Hritkanthadaha</b>	
• No <i>Daha</i>	0
• <i>Daha</i> of mild degree	1
• <i>Daha</i> of moderate degree relieved by cold Milk, drinks, antacids, food and vomiting.	2
• <i>Daha</i> of severe degree not relieved by cold milk, drinks, antacids, food and vomiting.	3
<b>2. Amla-Udgara</b>	
• No <i>Amla-Udgar</i> at all	0
• Occasional <i>Amla-Udgar</i> during day	1
• Continuous mild <i>Amla-Udgar</i>	2
• Continuous severe and excessive <i>Amla-Udgar</i>	3

**3. Utklesha**

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

**4. Avipaka**

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

**5. Vaman**

- No vomiting 0
- Feels sense of nausea and vomits occasionally 1
- Frequency of vomiting between four to six per week and increases when pain is aggravated 2
- Frequency of vomiting daily after every meal 3

**6. 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

**7. UdarAdhman**

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

**8. Klama**

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

work

**9. 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

**10. Guru Koshtha**

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

**11. 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

**12. 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

**B. Objective criteria:**

- C B C
- L F T (S.billirubin i.e. direct & 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

**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 has 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 & OBSERVATION:**

**EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS:**

1. **Hritkanthadaha (Retrosternal burning):** It was present in 65% patients. In *Amlapitta* there is burning sensation in retrosternal area, sometimes it may present to whole body. It depend upon extent of *Pitta*. If *Pitta dusti* 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. 73.66% relief was found. Results were statistically highly significant .

**2. Amlodgar(Sour and bitter Belching):**It was recorded in 50% patients. 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*. 76.92% relief was observed. Results were statistically highly significant ( $p < 0.001$ ).

**3. Utklesha(Nausea):** 55% patients were having *Utklesha*. After treatment 66.64% relief was assessed. Results were significant statistically ( $p < 0.01$ ).

**4. Avipaka (Indigestion):** 65% in 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 was assessed. Results were statistically highly significant.

**5. Vaman (Vomiting):** Vaman was present in 60% patients. In this symptom 26.34% relief was observed. This data suggests insignificant results ( $p > 0.05$ ).

**6. Aruchi(Loss of appetite):**It was reported in 85% patients. 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. This data suggests highly significant results ( $p < 0.001$ ).

**7.Udaraadhaman (Flatulence):** 90% patients 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. Results were highly significant statistically.

**8. Klama (Mental fatigue):**It was found in 35% patient. *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. The result was statistically insignificant.

**9. Vidbheda (Loosemotions) :** *Vidbheda* was reported in 65% patients. There is *Atipravritti* or *Apravrithi* of *doshain Ajeerna*. *Vatadusti* and *Agnimandya* are the main responsible factors for developing *Vidbheda*. 66.63% relief was observed in patients . The result was statistically highly significant ( $p < 0.001$ ).

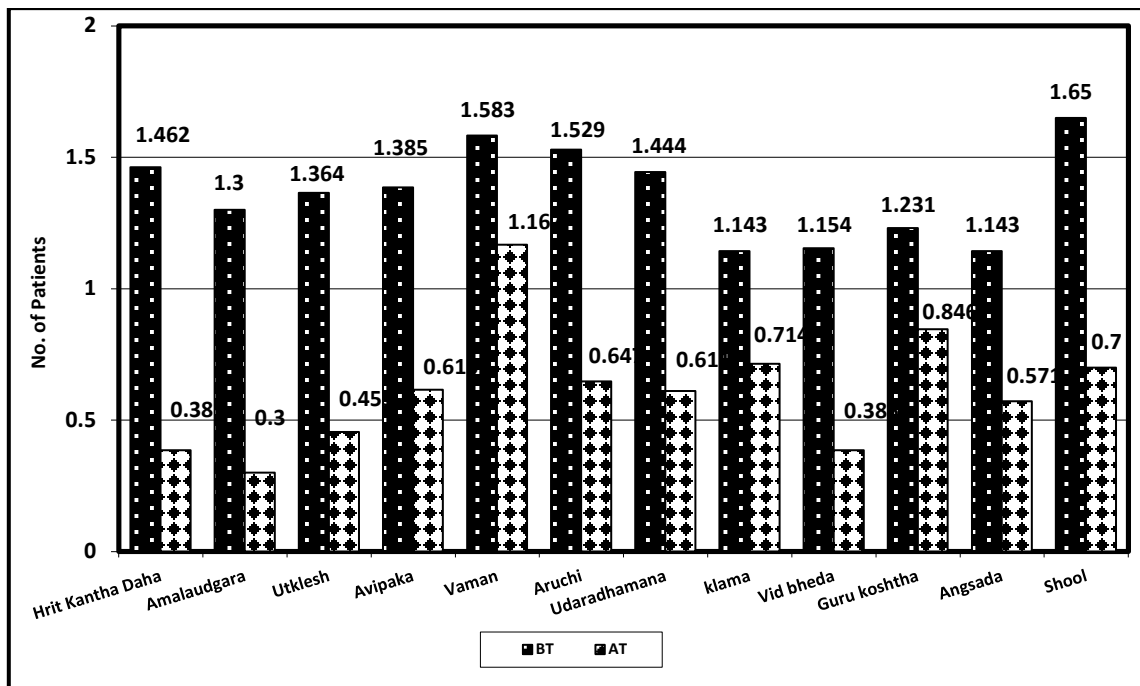


**10.Guru koshtha (Heaviness in abdomen):** 65% were suffering from *Mandagni* and vitiation of the *dosha* peculiarly, *Ama* or *Kapha* are responsible for producing this symptom, *Gurukoshkata*. There is also delayed gastric emptying. In this symptom 31.27% relief was assessed. The result was statistically significant ( $p < 0.05$ ).

**11.Angsada (Exhaustion):** It was present in 35% patients and 49.95% relief was found. The result was statistically insignificant ( $p > 0.05$ )

**12.Shoola (Pain) :** *Shoola* was found in 100% patients and 57.57% relief was observed for this symptom. The result was statistically highly significant ( $p > 0.001$ ).

**Fig. No. Q- Graphical presentation of subjective parameters (Before and after treatment)**



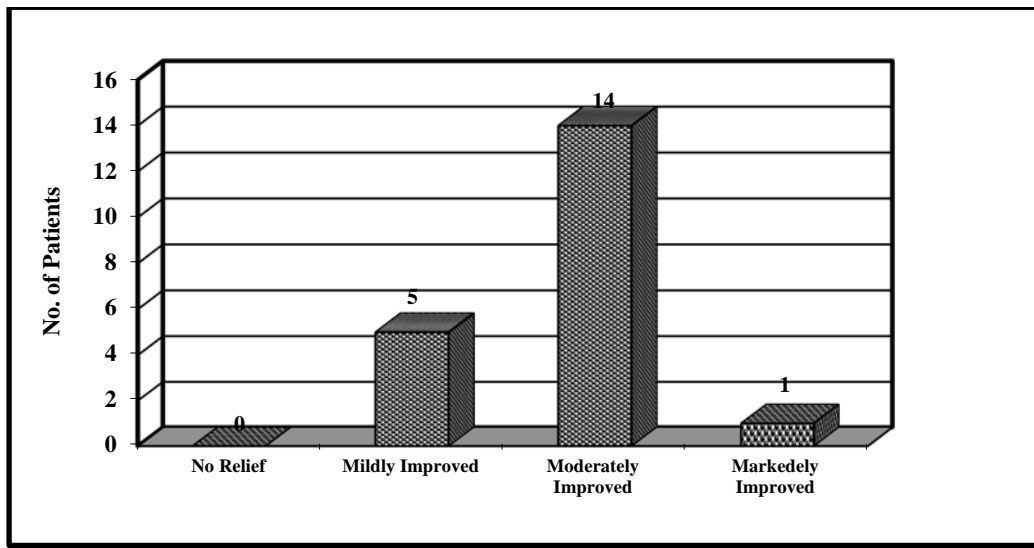
**B). EFFECT OF THERAPY ON OBJECTIVE PARAMETERS:**

Effect of therapy on objective parameters were within normal limits and the difference in the mean score values of blood investigations before and after treatment was statistically insignificant ( $p > 0.05$ ). Routine and microscopic examination of urine showed no effect before and after the treatment.

**OVERALL EFFECT OF THERAPY:**

Category of improvement		
	No. of pts.	% age
No relief	0	0%
Mildly improved	5	25%
Moderately improved	14	70%
Markedly improved	1	5%

In 20 patients, 5 patients were mildly improved, 14 patients moderately improved and 1 patient was markedly improved.



**DISCUSSION:** The pathogenesis of *Amlapitta* involves three important factors i.e. *Agnimandya*, *Ama* & *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 & *Agnimandya*. *Amashodhana* is done by *Mridu Vaman*, *Mridu Virechana*, *Anuvasana* & *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*, *Sheeta Veerya*, *Madhura Vipaka*. These are predominately *Vata-Pitta Shamaka* & 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<sup>6</sup>.

All contents of this 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 *Pitta shamaka*, *kaphashamka* and also *Vatashamaka* properties along with *Deepana*, *Pachana*, *Rochana* action.

**CONCLUSION:** All *Doshas* involved in *Amlapitta* but there is main predominance of *Pitta Dosha*. Due to *Nidana sevan*, *Vatadi dosha* get vitiated which leads to *Agnimandya*. Due to *Agnimandya* whatever is consumed remains *Vidagadha/undigested*. This *Vidagadha Anna* ultimately becomes *Shukta i.e. Amlabhava* of *Anna* takes place (due to fermentation) and lies in *Amashaya* as stagnant. If due to exposure to *Pitta Vardhak Aahar – Vihar*, *Pitta* gets further vitiated, it gets mixed with *Shukta Anna* and *Amlapitta* with its cardinal symptoms is then exhibited<sup>7</sup>. The diagnosis can be made on the basis of *Lakshana* and *Upashaya-Anupashaya*. Specific description about *Upashaya* and *Anupshaya* is given only by *Acharya Kashyapa* while describing *Doshaja* types of *Amlapitta*<sup>8</sup> The outcome of clinical study was significant statistically. Selected *drugs* showed better results with its *Pitta Shamaka and Deepana-Pachana* properties. It is to be advised to the patient to avoid such etiological

factors of *Ahara* and *Vihara* which are responsible for the causation of the disease. A patient of *Amlapitta* should avoid food items having *Lavana*, *Katu*, *Amla*, *Ushna*, *Tikshna* and *Vidahi* properties. *Viruddha Ahara sevana*, *Vegavidharana*, *Vishamashana*, *Bhukte Divaswapa* etc. must be avoided.

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