

A Clinical Study to Evaluate the Efficacy of Syrup Patoladi on Amlapitta in children

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ABSTRACT:

Amlapitta one of the most common diseases of GIT tract has been a burning clinical problem for many years affecting a large percentage population of the society. Due to change in lifestyle, there is vitiation of *Agni* which result in *Amlapitta*. *Madhava Nidana* describe was first one to describe it as *Amlapitta* and classify it on *Gati* basis¹ but the detailed explanation available in *Kashyapa Samhita*, for the first time as *Shuktaka*.² A clinical study was adopted in the clinical trial. 20 patients fulfilling the diagnostic and inclusion criteria were selected. The main objective of the clinical trial was to understand the concept of *Amlapitta* in *Ayurveda* & modern texts. In pediatric age group, strong *Shodhana* therapy is not advised due to possible complications and growing age period. The choice should be *Shamana chikitsa* with suitable drugs, which can pacify the *Pitta*. Keeping this in consideration, only *Samshamana* therapy is considered as therapeutic regime in the present study without any dropout, the children 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.

Keywords: *Amlapitta*, *Syrup Patoladi*, *Gati*, *Shuktaka*, *Shodhana*, *Shamana*, *Pitta*, *Chikitsa*.

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 & prevents the diseases.

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To have a better comprehension of pathogenesis of a disease, it is a requisite to associate the diseases, which are mentioned in the ancient classic texts with the diseases in present scenerio, but it is very difficult to co-relate disease with modern context, but now a days it is

a need of time to correlate the things. However the signs and symptoms of *Amlapitta* are very much similar to the disease mentioned in modern science as Acid-Peptic disorders. Peptic ulcers (gastric and duodenal ulcers) have similar symptoms related to *Amlapitta*, but the pathophysiology and histopathology said that ulcer's can't be included in *Amlapitta*. It may be complication of *Amlapitta*. So, the acid peptic disease without peptic ulcer can be included in *Amlapitta*. On the basis of symptoms, pathophysiology of the disease, it may be Acid Peptic Disorder specially Non-ulcer dyspepsia in the present scenario. Its treatment is very difficult because usually the patients cannot follow the *Pathya – Apathya* all the time especially children. *Ayurveda* has a lot to offer in the management of G.I.T. disorder. Many single and compound drugs have been tried on *Amlapitta*. The biggest challenge in pediatric practice is the acceptance of drug by the child under treatment. It is very commonly seen that some forms of drugs like powders (*Churna*), tablets (*Vati*, *Gutika*) and decoction (*Kwatha*) are lesser acceptable in children of younger age group. For the successful assessment of effects of a therapy, it becomes of prime importance that the selected mode of drug dosage is more and more acceptable in children. The appearance, smell and most importantly the taste of the drug will decide its acceptability. So considering all these points Syrup *Patoladi* has been selected for present study.

AIMS AND OBJECTIVES:

- i. To analyse the prevalence of *Amlapitta* in children.
- ii. To study the efficacy of Syrup *Patoladi* 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*.

Syrup Patoladi

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Method of preparation:

- Raw drug was taken and cleaned properly than made into *Yavakuta* form.
- Decoction of the drug was prepared according to *Sharnghadhara Samhita* by putting sixteen times of water and reduced to 1/4th part and filtered properly.
- 67.6% of *Sita* by weight added to the decoction, again boiled, reduced further to 1/2 part and filtered in very fine mesh thrice.
- The boiling process was continued until the syrup became one tari (thread).
- Again syrup was filtered in muslin cloth.

- Preservatives—sodium benzoate 4% and propyl paraben 0.1/% were added.
- Finally prepared syrup filled in clean, sterilized 400 ml bottles for dispensing.

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
1. Hritkanthadaha	
• 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
2. Amla-Udgara	
• 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 work 3

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:

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:

$$\text{Total BT} - \text{Total AT}$$

Total BT

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 60%. 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. 66.68% relief was found. Results were statistically highly significant ($p < 0.001$).

2. Amlodgar (Sour and bitter Belching): It was recorded 45%. Normal *rasa* of *Pitta* is *Katu*, but when it become *vidhgda*, *katu rasa* is changed into *Amla*. *Amla* and *dravaguna* of *pitta* leads to *Amlodgara* and *Utklesh*. 36.33% relief was observed. Results were statistically significant ($p < 0.05$).

3. Utklesha (Nausea): 45% patients were having *Utklesha*. After treatment 25% relief in was assessed. Results was insignificant ($p > 0.05$).

4. Avipaka (Indigestion): 60% patients 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. 26.34% relief was assessed. Results were statistically significant for group II ($p < 0.05$).

5. Vaman (Vomiting): Vaman was present in 65% patients. In this symptom 36.79% relief was observed. This data suggests statistically significant ($p < 0.01$).

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*. 38.45% relief was observed. This data suggests significant result ($p < 0.01$) statistically.

7. Udaraadhaman (Flatulence): 85% 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 38.45% relief. Results were significant ($p < 0.01$).

8. Klama (Mental fatigue): It was found in 30%. *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 50.03% relief was observed. The result was statistically insignificant ($p < 0.05$).

9. Vidbheda (Loose motions) : *Vidbheda* was reported in 60%. There is *Atipravritti* or *Apravrithi* of *doshain Ajeerna*. *Vatadusti* and *Agnimandya* are the main responsible factors for developing *Vidbheda*. 22.65% relief was observed. The result was statistically insignificant ($p > 0.05$).

10. Guru koshtha (Heaviness in abdomen): 60% patients 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 26.34% relief was assessed. The result was statistically significant ($p < 0.05$).

11. Angsada (Exhaustion): It was present in 40% patients. 41.66% relief was found. The result was statistically significant ($p < 0.01$).

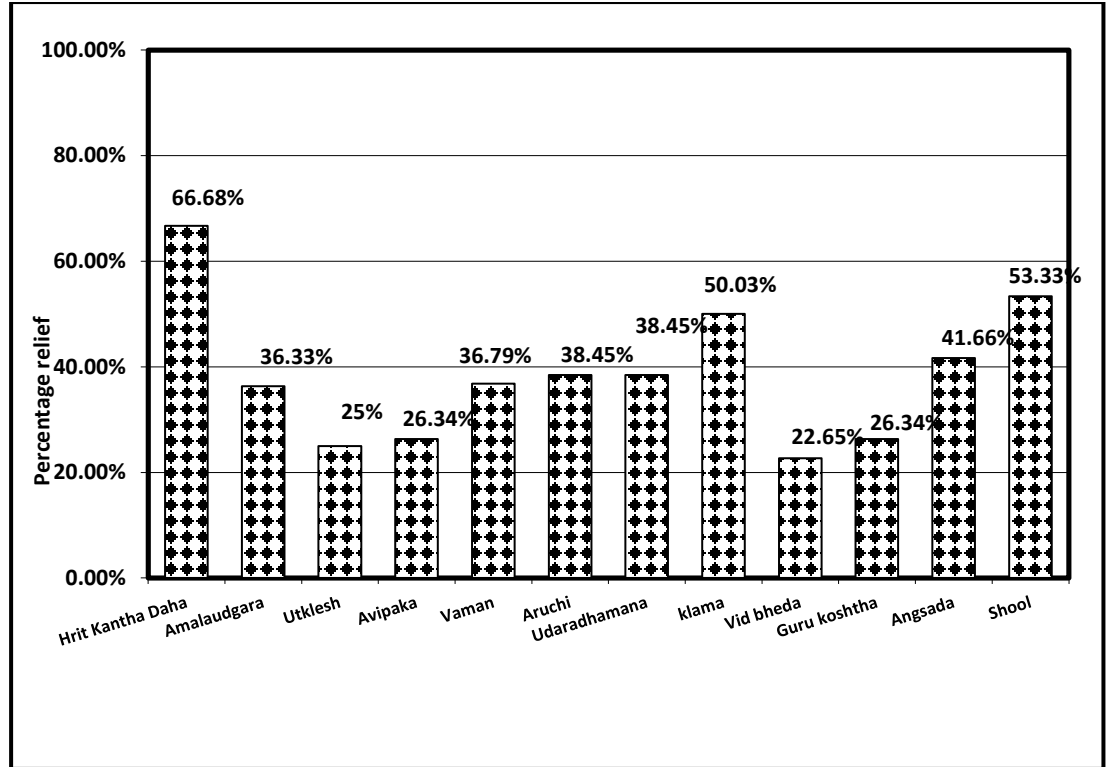
12. Shoola (Pain) : *Shoola* was found in 100% patients. In group-I 53.33% relief was observed for this symptom. The result was statistically highly significant ($p > 0.001$).

B). EFFECT OF THERAPY ON OBJECTIVE PARAMETERS:

Effect of therapy on objective parameters was 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.

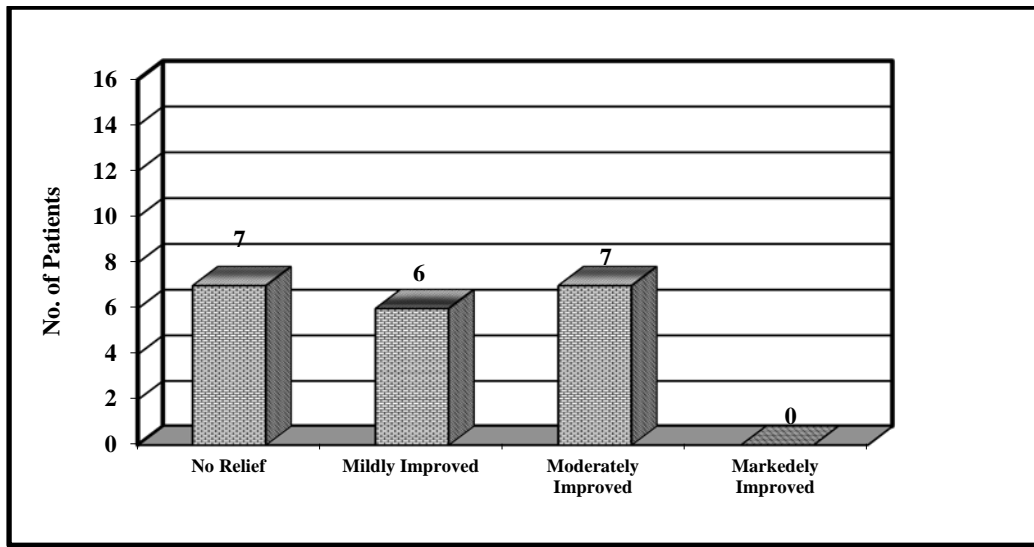
GRAPHICAL PRESENTATION ON SUBJECTIVE CRITERIA



OVERALL EFFECT OF THERAPY:

Category of improvement		
	No. of pts.	% age
No relief	7	35%
Mildly improved	6	30%
Moderately improved	7	35%
Markedly improved	0	0%

In 20 patients, 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 0 % patients showed marked improvement, 35% patients were moderately improved, and 30% patients showed mild improvement and 35 % patients showed no improvement.



DISCUSSION: Diet plays a major role in *Amlapitta*, so dietary intervention has much benefits in this disease. Main line of treatment is to correct *Ama* formation & *Agnimandya*. *Amashodhana* is also done by *Deepana* and *Ama Paachan* with the relevant herbs and medicines along with *Vaman*, *Virechan* etc. In this case we have selected syrup *Patoladi* and 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 *Laghu* gunas of *Pitta Dosha*. *Madhura Rasa* is *Pitta Vata Shamaka*⁵. *Madhura Rasa* is also having *Manaprasadan Guna*⁶ and due to this it also counters the *Manshikha Bhava*. *Tikta* and *Kashaya Rasa* have *Ruksha*, *Sheeta* properties⁷. 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 *Amapachana 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 in digestion of *Ama*.

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Madhura vipaka 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 *Pitta shamaka* 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*. Selected drugs showed better results with its *Pitta Shamaka* and *Deepana-Pachana* properties. Moreover diet that is predominant in *Tikta*, *Kashaya* and *Madhura rasa* and *Avidahi*, *Pitta-Kapha Shamaka* properties should be used by the patient of *Amlapitta* and the diet predominant in *Katu-Amla-Lavana Rasa*, *Guru- Ushna* and *Tikshna* properties should be avoided.

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