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# "A RANDOMIZED COMPARATIVE OPEN CLINICAL TRIAL ON THE EFFECT OF YAVADI KWATH AND PATOLADI KWATH IN THE MANAGEMENT OF AMLAPITTA."

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**Abstract:** Amlapitta is a very common disease which can be corelated with Hyperacidity. It is caused by an imbalance between the acid secreting mechanism of the stomach and proximal intestine and the protective mechanisms that ensure their safety. Amlapitta is disorder caused by habitual, irregular diet schedule and activities but also because of psychological and physiological disorder including Ahar, vihar. **Objectives:** To evaluate the efficacy of *Yavadi Kwath* and *Patoladi Kwath* in Amlapitta. To compare the efficacy of Yavadi Kwath and Patoladi Kwath in the management of Amlapitta. Methods: It is a Randomized Comparative open clinical study of trial. In this study, total 44 patients of 'Amlapitta' were taken. Patients of Group-A were administered Yawadi Kwath and in Group B patients were administered Patoladi kwath 40 ml twice a day before food in the morning and evening for the period of 30 days. **Results:** In most of the patients, it was observed that Agnimandya and dietic faulty habit are the main responsible factor for Amlapitta. It was observed that in the Symptoms of Amlapitta like Avipak, Klama, Amlodgar, Utklesh, Gaurav, Daha and Aruchi it was significant difference was noted between follow up in both the group on day 15 and day 30. However, the percentage relief was more in Group A as compare to Group-B. **Conclusion**: Intervention of both Group A and Group B is found equally effective statistically for the symptoms like, Klama, Amlodgar, Utklesh, Gaurav, Daha and Aruchi except Avipak.

**Keywords**: Amlapitta, Yawadi Kwath ,Patoladi kwath, Klama, Amlodgar

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#### Introduction:

Today's life style is completely changed by all the means our diet pattern, life styles, behavioural pattern has been changed and it is not suitable for our normal physiology of digestion of body. *Amlapitta* is a very common and troublesome disease. Amlpaitta can be corelated with Hyperacidity refers to a set of symptoms caused by an imbalance between the acid secreting mechanism of the stomach and proximal intestine and the protective mechanisms that ensure their safety.

In Brihatrayees, Amlapitta was not considered or grouped under any specific disease, but the symptoms are mentioned. In Laghutrayees description regarding Nidana, Samprapti and Lakshaanas(Symptoms) are available. The disease under the heading Amlapitta with the symptoms like Avipaka, Klama, Utklesha. Hritkanthadaha, Tiktaamlodgara, makes the person to consult physician. <sup>1</sup>According to Ayurveda, Agni is accountable for Ayu (age), Varna (colour), Bala (power), Swasthya Utsaha (excitement), (health), Upachaya (digestion), Prabha, Oja and Teja and Agni takes a axis role in the etiopathogenesis of all human illnesses.<sup>2</sup> Continuous indulgence in improper diet and erratic lifestyle basically aggravates Pitta Dosha which leads the disease into acute condition of Vidagdhajirna (indigestion) which due ignorance in turn converts into Amlapitta.3,4 The improper living style and faulty diet habits generates the imbalance of the body elements vata, pitta & kapha and thus various disorders may occur. 5 Due to this change

life style, many people are suffering from dyspepsia. Change in function of Agni leads to various diseases. It is common for many of us to face a burning sensation in stomach and chest at times. The prevalence rate of Gastritis in India is around 10 million. Amlapitta is disorder caused by habitual, irregular diet schedule and activities but also because of psychological and physiological disorder as due to Ahar, vihar, fast food and drink that are incompatible, spoiled, very sour and that can cause vitiation of pitta and increases of drava and amlaguna of pitta.

Yawadi Kwath<sup>8</sup> is combination of Yava, Pippali, Patolpatra has been given in Yogratnakar and Patoladi Kwath<sup>9</sup> is combination of Patolpatra, Triphala, Nimbatwak has been given in Chakradatta along with Koshna Jala for the Amlapitta. So, it needs to study the Clinical trial of Yavadi Kwath and Patoladi Kwath in Amlapitta.

#### **Objectives:**

- 1. To evaluate the efficacy of *Yavadi Kwath* in management of *Amlapitta*.
- 2. To evaluate the efficacy of *Patoladi Kwath* in management of *Amlapitta*.
- 3. To compare the efficacy of *Yavadi Kwath* and *Patoladi Kwath* in the management of *Amlapitta*.

#### **Materials and Methods**

**Study design –** A Randomized Comparative open clinical study of trial.

**Sample size**- Minimum of 40 patients of either sex age group 18 -65 yrs. were selected.

#### POSOLOGY: Table no. 1

Particulars	GROUP-A	GROUP-B		
No.of patients	20	20		
Drug	Yavadi kwath	Patoladi kwath		
Anupan	Koshna jala	Koshna jala		
Dose	40 ml twice a day before food.	40 ml twice a day before food.		

Duration	30 days	30 days		
Follow up	15, 30 days	15, 30 days		

#### **OBSERVATION PERIOD -**

Follow up -15<sup>th</sup>, 30<sup>th</sup> days. Total study duration 30 days.

#### a) INCLUSION CRITERIA

- Patients between age group of 18 to 65 years of either gender.
- Patients with clinical signs and symptoms of Amlapitta (Avipaka, Utklesha, Hrullas, Tikta-Amla udgara, Hridkanthadaha).

#### b) **EXCLUSION CRITERIA**

- Patient suffering from any chronic systemic disorder.
- Any other addictions like chronic alcoholism induced hyperacidity.
- Pregnant women's, Lactating mothers.
- Patient having bleeding disorder

#### **Observation and Results:**

In this study, total 44 patients of 'Amlapitta' were taken. However, 04 patients were not coming for follow up and they dropped out. Patients of Group-A were administered *Yawadi Kwath* 40 ml and in Group B patients were administered *Patoladi kwath* 40 ml twice a day before food in the morning and evening for the period of 30 days.

#### **Results:**

#### **Gender:**

In this study, totally 22[55%] were male patients and 18[45%] were female while more male was recruited in the study it may be due random selection of patients.

#### Age:

As per inclusion criteria of patients were selected having age between 18 years to 65 yrs. and distributed it in four-sub age groups. Out of 40 patients' number of patients found in age group 18-30 were 11[27.5%] while 16[40%]

patients observed in age group 31-40 yrs., 06 [15%] patients observed in age group 41-50 yrs., 06 [15%] patients observed in age group 51 to 60 yrswhile 01[2.5%] patient from age group 60-65 of Amlapitta was observed.

#### Diet:

Out of 40 patients, 34[85%] were having mixed type diet habit while 06[15%] were purely vegetarian.

#### **Prakruti:**

Out of 40 patients, 13[36.67%] patients were having Vata-pittaj prakruti, 11[27.5%] patients were having of Pitta-kaphaj prakruti,09[22.5%] patients were kapha-pittaj prakruti while 7[17.5%]patients were having of Vata-kaphaj prakruti.

#### **Clinical results:**

## Friedman Test (Repeated measure nonparametric test) for subjective criteria of Amlapitta in Group-A:

Friedman Test (Repeated measure non-parametric test) is applied due to observation are matched within group, on every follow up i.e. Day 0, Day 15 and on Day 30 to see the effect of intervention for this parameter, the p value observed is < 0.0001 which is highly significant among the follow ups for the symptoms Avipak, Klama, Amlodgar, Utklesh, Gaurav, Daha and Aruchi on day 15 and day 30.

## Friedman Test (Repeated measure nonparametric test) for subjective criteria of Amlapitta in Group-B:

Friedman Test (Repeated measure nonparametric test) is applied due to observation are matched within group, on every follow up i.e. Day 0, Day 15 and on Day 30 for the Group B to see the effect of intervention for this parameter, the p value observed is < 0.0001 which is highly significant among the follow ups for the symptoms Avipak, Klama, Amlodgar, Utklesh, Gaurav, Daha and Aruchi on day 15 and day 30.

# Comparison done within each follow up by applying Dunn's multiple comparisons test in Group-A

#### 1. Avipaka:

The effect was seen moderately significant on Day 15 as compare to Day 0 as p value obtained was <0.01 and highly significant on Day 30 as p value was <0.001. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was highly significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

#### 2. Klama

The effect was not significant on Day 15 as compare to Day 0 as p value obtained was >0.05 and moderately significant on Day 30 as p value was <0.01. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was moderately significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

#### 3. Amlodgar

The effect was seen considerably significant on Day 15 as compare to Day 0 as p value obtained was <0.05 and moderately significant on Day 30 as p value was <0.01. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was moderately significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

#### 4. Utklesh

The effect was seen moderately significant on Day 15 as compare to Day 0 as p value obtained was <0.01 and highly significant on Day 30 as p value was <0.001. However, p value

obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was highly significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

#### 5. Gaurav

The effect was seen considerably significant on Day 15 as compare to Day 0 as p value obtained was <0.05 and highly significant on Day 30 as p value was <0.001. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was moderately and highly significant difference in Symptom score for this symptom of Amlapitta on Day 15 and 30 respectively as compare to Day 0.

#### 6. Daha

The effect was seen considerably significant on Day 15 as compare to Day 0 as p value obtained was <0.01 and highly significant on Day 30 as p value was <0.001. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was moderately and highly significant difference in Symptom score for this symptom of Amlapitta on Day 15 and 30 respectively as compare to Day 0.

#### 7. Aruchi

The effect was not significant on Day 15 as compare to Day 0 as p value obtained was >0.005 and moderately significant on Day 30 as p value was <0.01. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was moderately significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

Comparison done within each follow up by applying Dunn's multiple comparisons test in Group-B

#### 1. Avipak

The effect was seen moderately significant on Day 15 as compare to Day 0 as p value obtained was <0.01 and considerably significant on Day 30 as p value was <0.05. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was considerably significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

#### 2. Klama

The effect was not significant on Day 15 as compare to Day 0 as p value obtained was >0.05 and moderately significant on Day 30 as p value was <0.01. However, p value obtained was >0.05 which is not significant on Day 15 compared to day 30. So, it can be concluded that there was moderately significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

#### 3. Amlodgar

The effect was moderately significant on Day 15 and Day 30 as compare to Day 0 as p value obtained was <0.01. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was moderately significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

#### 4. Utklesh

The effect was not significant on Day 15 as compare to Day 0 as p value obtained was >0.05 and considerably significant on Day 30 as p value was <0.05. However, p value obtained was >0.05 which is not significant on Day 15 compared to day 30. So, it can be concluded that there was

considerably significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

#### 5. Gaurav

The effect was not significant on Day 15 as compare to Day 0 as p value obtained was >0.05 and considerably significant on Day 30 as p value was <0.05. However, p value obtained was >0.05 which is not significant on Day 15 compared to day 30. So, it can be concluded that there was considerably significant difference in Symptom score for this symptom of Amlapitta on Day 30 as compare to Day 0.

#### 6. Daha

The effect was seen considerably significant on Day 15 as compare to Day 0 as p value obtained was <0.05 and moderately significant on Day 30 as p value was <0.01. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was considerably and moderately significant difference in Symptom score for this symptom of Amlapitta on Day 15 and 30 respectively as compare to Day 0.

#### 7. Aruchi

The effect was seen considerably significant on Day 15 as compare to Day 0 as p value obtained was <0.05 and moderately significant on Day 30 as p value was <0.01. However, p value obtained was >0.05 which is not significant on Day 15 and Day 30. So, it can be concluded that there was considerably and moderately significant difference in Symptom score for this symptom of Amlapitta on Day 15 and 30 respectively as compare to Day 0.

Table No.2 Comparison for Subjective Criteria between the groups by Mann-Whitney 'U' Test

No	Symptoms	Mean ± SD		Median		Mann-Whitney		P Value
		Group -A	Group -B	Gr.A	Gr.B	U'	U	
1	Avipak	1.4±0.9	0.7±0.9	2	1	270.5	129.5	0.05

2	Klama	0.9±1.0	0.8±0.8	1	1	205.5	194.5	0.89
3	Amlodgar	1.1±0.7	1.0±0.8	1	1	218	182	0.63
4	Utklesh	1.1±0.8	0.8±1.1	1	1	237	163	0.31
5	Gaurav	1.3±0.8	0.8±1.1	1	1	252.5	147.5	0.15
6	Daha	1.3±0.8	1.0±0.9	1	1	248	152	0.19
7	Aruchi	1.2±1.0	1.0±0.9	1	1	225.5	174.5	0.49

Difference The between before intervention and after intervention score of both groups compared by 'Mann-Whitney U Test'. It was found that the sum of rank for the symptom Avipak, Mann Whitney U' statistics was 270.5, Test statistic (U) was 129.5, where the test statistic U was lies between Population Mean ±1.96 SD which was consider as significant at 5% level of significance. (P<0.05) Therefore the difference between Symptom Score of Avipak, of Group-A and Group B is statistically significant, so therefore we can conclude that in the symptom Avipak, Group A is better compare to group B as mean reduction was more in Group A. However, in the Symptoms Klama, Amlodgar, Utklesh, Gaurav, Daha and Aruchi the difference was not significant at 5% level of significance as the p value > 0.05 hence in these symptoms also Group A and Group B intervention is found equally effective statistically.

# Percentage of Relief (Subjective Criteria) in Each Symptom of 40 Patients of Amlapitta Percentage of Relief:

In Group A, the percentage of relief noted in the symptom *Avipak* on day 15 was 62.9% while on day 30 relief was 80%, in the symptom *Klama* the percentage of relief on day 15 was 57.1% while on day 30 relief was 75%, in the symptom **Discussion:** 

The 'Amlapitta' is composed of word Amla and Pitta. The term Amla has been used as

Amlodgar the percentage of relief on day 15 was 63.3% while on day 30 relief was 73.3%, in the symptom *Utklesh* the percentage of relief on day 15 was 69% while on day 30 relief was 75.9%, in the symptom *Gaurav* the percentage of relief on day 15 was 66.6% while on day 30 relief was 78.8%, in the symptom *daha* the percentage of relief on day 15 was 52.9% while on day 30 relief was 79.4% and in the symptom *Aruchi* the percentage of relief on day 15 was 48.4% while on day 30 relief was 80.6%.

In Group B, the percentage of relief noted in the symptom Avipak on day 15 was 50% while on day 30 relief was 44.1%, in the symptom Klama the percentage of relief on day 15 was 34.5% while on day 30 relief was 58.6%, in the symptom Amlodgar the percentage of relief on day 15 was 57.6% while on day 30 relief was 60.6%, in the symptom *Utklesh* the percentage of relief on day 15 was 37.5% while on day 30 relief was 50%, in the symptom Gaurav the percentage of relief on day 15 was 34.3% while on day 30 relief was 45.7%, in the symptom daha the percentage of relief on day 15 was 43.2% while on day 30 relief was 54.1% and in the symptom Aruchi the percentage of relief on day 15 was 46.9% while on day 30 relief was 62.5%.

an epithet to Pitta. Though, the Amla has been said a natural property of Pitta along with Katu-Rasa according to Charaka (Ch. Su. 1/60).

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Sushruta has enlisted Katu as its original rasa and mentioned that when Pitta becomes Vidagdha then it changes into Amla. (Su. Su. 21/1). Amlapitta is mentioned in Madhava nidana, Kashyapa Samhita, Bhavaprakasa and Chakradatta. Acharya Charaka, Sushruta and Vagbhata have not described about Amlapitta, as separate though it has been referred at certain places in treatise.

The pathogenesis of amlapitta involves three important factores i.e. Agnimandya, Ama & Annavaha Strotodushti. Along with this, the vitiation of pitta leading to quantitative & qualitative increase of pachaka pitta especially in its ama & drava guna gives rise to amlapitta. Excessive intake of Amla (sour), Katu (Pungent), Lavan (Salty), Vidahi (Spicy) substances causes vitiation of Pittadosha and lead to disease Because of Hetu Sevena, Mainly Amla & Drava Guna of Pachakapitta increases. These increased Amlata and Dravata produce Agnimandya, which further leads to Avipaka and Rasadushti. Avipaka gives rise to Vidagdhata of Pitta, while Rasa Dushti generates Ama, which once again produces Vidagdhata in Pitta. Both (Vidagdhata & Ama) further Vitiates Jatharagni leads to Agnimandya thus this Vicious Cycle continues and produce the disease Amlapitta.

#### Scope of study:

Yawadi kwath and Patoladi Kwath and pharmacokinetic study can be planned to study it potential in hyperacidity at cellular level. Pharmaceutical study Yawadi kwath and Patoladi Kwath can be planned to timely release of drug and action like sustained release tablets.

#### **Limitation of study:**

This study can be done on larger sample so that findings of study can be generalized.

#### **Conclusion:**

In most of the patients, it was observed that Agnimandya and dietic faulty habit are the main responsible factor for Amlapitta. It was observed that in the Symptoms of Amlapitta like Avipak, Klama, Amlodgar, Utklesh, Gaurav, Daha and Aruchi it was significant difference was noted between follow up in both the group on day 15 and day 30. However, the percentage relief was more in Group A as compare to Group-B Average percentage of relief in all symptoms in Group a 68.37% while in group it 48.54%. However statistically it was Group A and Group B intervention is found equally effective statistically for the symptoms like, Klama, Amlodgar, Utklesh, Gaurav, Daha and Aruchi except Avipak. The duration of treatment should be 30 days for Amlapitta with this intervention for the better results.

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