EFFECT OF NISTHUSHAYADIKWATHA AND PHALATRIKADI KWATHA IN AMLAPITHA- A RANDOMISED COMPARATIVE CLINICAL STUDY

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ABSTRACT

Amlapitta may be a clinical entity manifesting within the Annavaha Srotas. Kashyapa and Madhava have described this disease thoroughly. Amlapitta has become quite common because of the changing lifestyle, dietary preferences and stressful life. It is characterized by Avipaka, Klama, Tiktodhgara, Amlodhgara, Gaurava, Hritkanthadaha, and Aruchi indicating the Vikruthi of Pachakapitta, Kledakakapha, and Samanavata. The etiological factors and therefore the symptomatology manifest relate Amlapitta to diseases mentioned under Acid Peptic Disorders. Nistushayadi Kwatha and Phalatrikadi kwatha were selected. The main objectives of the study are to study and compare the effect of Nistushayadi Kwatha and effect of Phalatrikadi kwatha in the management of Amlapitta.

A total of 40 patients who fulfilled the inclusion criteria were selected, and randomly assigned into two groups i.e., Group A and Group B, comprising of 20 patients each. Group A and Group B were administered Nistushayadi kwatha and Phalatrikadi kwatha respectively for 30 days. Both the groups were advised Pathya Ahara. They were followed up after every 10th day. After the intervention the Samanya Lakshana of Amlapitta were observed, recorded and assessed. The overall assessment of both the groups, where group A receives Nistushyadi kwatha and group B Phalatrikadi kwatha shows promising improvement in the subjective parameters. Assessment was done using unpaired ‘t’ test between these two groups, the result was not quite statistically significant which means there is no much difference in the efficacy of these two formulation in the management of Amlapitta. Both the formulations shown nearly same outcome in the improvement of disease parameter. The reduction in the symptoms were started to be noticed by 7th day where the patients had reduction in Hrutkantha Daha, Aruchi, Kanthadaha and Angagourav. These symptoms resolved by 30th day.

KEYWORDS: Amlapitta; Nistushayadi kwatha; Phakatrikadi Kwatha.

INTRODUCTION

The condition where the Ahara rasa after reaching to Ahasaya cause Vidaghdha of Pitta is called Amlapitta. It is a disease of Annavaha Srotas and is more common in the present scenario of unhealthy diets and regimen. It is the disease, where Vidagdha and Amla Yukta Rasa leading to Anna Vaha Srotos Dushti causes symptoms like Avipaka, Klama, Tiktodhgara, Gaurava, Hitrakanta Daha, and Aruchi[1] Amlapitta can be correlated with Hyperacidity or Acid Dyspepsia.

Importance of food has been explained by Acharya Charaka[2] which clearly states that all the Sharira, Manasika Sukha Dukha completely depends on food that we intake. Ahita Anna Bhojana disturbs Agni. Thus disturbed Agni, in turn disturbs the entire equilibrium of the body there by leading to many Vikaras. Shodana, Shamana and Nidana Parimarjana are the main line of treatment adopted by our Acharyas[3]. The management in modern science is usage of antacids, Proton Pump Inhibitors [PPIs], H2 receptors. Antacids works by neutralizing the amount of acid in the stomach[4]. Food and Drug Administration (FDA) warns that there is certain antacids cause an increased risk of fractures [5]. Long term use of these medicines produces vomiting, diarrhoea, weakness, low blood pressure, skin rashes[6]. Hence it's the need of the hour to develop better medicament to manage this condition. As these
medications doesn’t gives a permanent remedy and due to its high recurrence chances it is the need of the hour to find measures to overcome this burning problem through Ayurvedic system of medicine. The drug selected for the study aiming to reduce the Vidagdha and other Laxanas of Amlapitta are Nistushayadi Kwatha[7] and Phalatrikadi Kwatha[8].

MATeRIALS AND METHODS

A randomized comparative clinical study is done with a sample size of Total 40 patients selected in 2 groups. Group A: Patients will receive Nistushayadi Kwatha and Group B. Patients will receive Phalatrikadi Kwatha.

Inclusion criteria
1. Patients presenting with Lakshanas of Amlapitta.
2. 18 to 60 yrs of patients
3. Patients of either sex will be taken for study.

Exclusion criteria
1. Patients suffering from other systemic illness which interfere with the course of treatment.
2. Below 18yrs and above 60yrs.
3. Diagnosed case of Ulcerative Colitis, Perforated Ulcer, Crohn’s disease
4. Ca stomach.

Composition of trial drugs

Table 1: Nistushayadi Kwatha

| S.No. | Ingredients | Quantity |
|-------|-------------|----------|
| 1.    | Nistu [Yava] (Dehusked Barley) | 1 Part |
| 2.    | Vasa        | 1 part   |
| 3.    | Amlaki      | 1 part   |
| 4.    | Trijatakachoorna | 1 part |
| 5.    | Honey       | 1 part   |

Table 2: Phalatrikadi Kwatha

| S.No. | Ingredients | Quantity |
|-------|-------------|----------|
| 1.    | Haritaki    | 1 Part   |
| 2.    | Vibhataki   | 1 part   |
| 3.    | Amlaki      | 1 part   |
| 4.    | Patola      | 1 part   |
| 5.    | Kiratatikta | 1 part   |

A required dry drug for preparing Nistushayadi kwatha and Phalatrikadi Kwatha was procured from local market and pharmacy; taxonomist will authenticate it. Churnais prepared as per standard method. Nistushayadi kwatha and Phalatrikadi Kwatha was given to the patients along with respective Prakshepakadravya and method of Kwatha preparation is advised to prepare at home.

The Total Duration of Study: 30days (with follow-up on every 10th day). Nistushayadi Kwatha and Phalatrikadi Kwatha were given to patients 48 ml twice a day before meals.

Table 3: Subjective parameters and Criteria for the treatment are following

| Parameter               | No symptoms (0)                      | Mild (1)                                    | Moderate(2)                                 | Severe(3)                                    |
|-------------------------|--------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|
| Avipaka (Indigestion)   | Presence of all Jeernahar Laxanas    | Presence of any 4 Jeernahar Laxanas         | Presence of any 2 Jeernahar Laxanas         | No Jeernahar Laxanas                        |
| Amlodgar (Sour belching)| Absent                               | Appears 2-3 times/ days on consumption of food | Appears 4-6 times/days on consumption of any type of food | Appears more than 6 times/days on consumption of food |
| Angagorava (Fatigue)    | Absent                               | Feel of heaviness in Udara                  | Feel of heaviness associated with Avipaka   | Feel of heaviness associated with Klama      |
| Kanthadaha (Burning sensation in the chest) | Absent | Burning sensation in the throat region | Associated with Utklesha | Associated with Gastric regurgitation |
| Hritdaha (Burning sensation in cardiac region) | Absent | Retrosternal Discomfort | Associated with pain | Associated with Gastric regurgitation |
| Aruchi (Anorexia)       | Absent                               | Loss of interest in intake of food          | Aversion to the food                        | Nausea and sometimes Vomiting after intake of food |
RESULTS

In this study, effects of Nistushayadi Kwatha and Phalatrikadi Kwatha in the management of Amlapitta were registered for clinical trial and were categorized randomly into two groups consisting of 20 patients in each group according to inclusion criteria and each patient was observed and histories were noted, examinations were done thoroughly and noted.

Table 4: Chief complaints wise distribution of 40 patients of Amlapitta

| Chief complaints | No of patients | Total No. of patients (40) | Percentage |
|------------------|----------------|----------------------------|------------|
|                  | Group A | Group B |                        |            |
| Aruchi           | 20      | 20      | 40                       | 100        |
| Amlodgara        | 20      | 19      | 39                       | 97.5       |
| Kantha daha      | 20      | 18      | 38                       | 95         |
| Hrit daha        | 20      | 18      | 38                       | 95         |
| Angagorva        | 20      | 19      | 39                       | 97.5       |
| Avipaka          | 19      | 17      | 37                       | 92.5       |

Table 5: Effect of Nistushayadi Kwatha and Phalatrikadi Kwatha in the Management of Amlapitta

| Sl.no | Criteria   | Nistushayadi Kwatha (Group A) | Phalatrikadi Kwatha (Group B) |
|-------|------------|-------------------------------|-------------------------------|
| 1.    | Aruchi     | 61.53                         | 59.37                         |
| 2.    | Amlodgara  | 56.41                         | 55.17                         |
| 3.    | Kanthdaha  | 58.82                         | 44.44                         |
| 4.    | Hritdaha   | 65.38                         | 53.84                         |
| 5.    | Angagorava | 56.25                         | 50                            |
| 6.    | Avipaka    | 54.16                         | 50                            |

Table 6: Comparisons between Group A and Group B

| Parameters       | Reduction In Mean | SD Group A | SD Group B | SEM Group A | SEM Group B | T value | p Value | Significance at p < 0.05         |
|------------------|-------------------|------------|------------|-------------|-------------|---------|---------|----------------------------------|
| Aruchi           | 1.2               | 0.41       | 0.50       | 0.09        | 0.11        | 1.759   | 0.086   | Not quite statistically significant |
| Amlodgara        | 1.11              | 0.45       | 0.52       | 0.10        | 0.117       | 1.689   | 0.099   | Not quite statistically significant |
| Kantdaha         | 1                 | 0.46       | 0.6        | 0.103       | 0.134       | 2.366   | 0.0231 | Statistically significant         |
| Hritdaha         | 0.85              | 0.37       | 0.57       | 0.82        | 0.128       | 0.830   | 0.1807 | Not statistically significant     |
| Angagorava       | 0.9               | 0.55       | 0.44       | 0.124       | 0.099       | 0.159   | 0.350   | Not statistically significant     |
| Avipaka          | 0.65              | 0.49       | 0.51       | 0.109       | 0.114       | 1.268   | 0.212   | Not statistically significant     |
The overall assessment of both the groups, where group A receives Nistushyadi kwatha and group B Phalatrikadi kwatha shows promising improvement in the subjective parameters. Assessment was done using unpaired ‘t’ test between these two groups the result was not quite statistically significant which means there is no much difference in the efficacy of these two formulation in the management of Amlapitta. Both the formulations shown nearly same outcome in the improvement of disease parameter.

**DISCUSSION**

Total 47 patients of Amlapitta were registered. Among them 40 patients completed the study and 4 were dropouts. Based on the inclusion criteria the patients were selected for the study and randomly assigned into two groups comprising of 20 in each. The inclusion criteria and exclusion criteria were made giving due consideration to Samanya Lakshana of Amlapitta. The present study was conducted in Jangala Desha. 20 patients in each group and remaining 4 patients (2 in group A and 2 in group B) discontinued the treatment. The reason for discontinue is unknown.

The assessment of results were done by assessing the subjective parameters on grading by using specific grades as mentioned earlier in the clinical study. Assessment was done before the treatment, after the treatment and after the follow up of one month. The effect of the treatment shows promising improvement in the subjective parameters. By analyzing the result of the treatment on the basis of different parameters such as Aruchi, Amlodghara, Kanthdaha, Hrutdaha, Angaurava and Avipaka it shows that Nistushyadi kwatha and Phalatrikadi kwatha have good result and statistical significant shows there is no much difference in the efficacy of these two formulations in the management of Amlapitta.

**CONCLUSION**

The present study entitled, Effect Of Nistushyadi kwatha and Phalatrikadi Kwatha In Amlapitta- A Randomized Comparative Clinical Study was carried out on 40 patient of Amlapitta.

The present study was a comparative clinical study with pre-test and post-test design wherein 40 patients of irrespective of sex, religion, work and socio-economic status of Amlapitta were selected and randomly assigned into two groups comprising of 20 patients in each group. Patients of Group A were administered Nistushyadi Kwatha and patients of Group B were administered Phalatrikadi Kwatha in the dose of 48ml.

The study revealed that;

- Maximum patients were female patients belonging to lower middle socio-economic status, Hindu religion, married, having mixed diet presenting with the maximum Samanya Lakshana of Amlapitta, with average duration of 1 to 2 years. Nistushyadi Kwatha and Phalatrikadi Kwatha are effective in Amlapitta to achieve the results as Shamana Prayoga.

The overall assessment of both the groups, where group A receives Nistushyadi kwatha and group B Phalatrikadi kwatha shows promising improvement in the subjective parameters. Assessment was done using unpaired ‘t’ test between these two groups the result was not quite statistically significant which means there is no much difference in the efficacy of these two formulation in the management of Amlapitta. Both the formulations shown nearly same outcome in the improvement of disease parameter.

The reduction in the symptoms were started to be noticed by 7th day where the patients had reduction in Hrutkantha Daha, Aruchi, Kanthdaha and Angagourav. These symptoms resolved by 30th day. The Avipaka appeared in 2patients during the follow-up period and Amlodghara for 1 patient.

| Parameters                        | Reduction in Mean | SD          | SEM         | Group A | Group B | SEM         | SED          | T value | p Value | Significance at p< 0.05 |
|-----------------------------------|-------------------|-------------|-------------|---------|---------|-------------|--------------|----------|---------|------------------------|
| Overall Assessment Between the groups | 0.9517            | 0.7167      | 0.1965      | 0.1780  | 0.0802  | 0.0726      | 0.108        | 2.1713   | 0.0551   | Not quite statistically significant |
Pictures of Experimental Study

**Ingredients of Nishtushayadi kwatha**

**Ingredients of Phalatrikadi kwatha**

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**Cite this article as:**

Maumita Halder, Prashant V Kulkarni, Abhijit Shinde, Binu.M.B. Effect of Nisthushayadikwatha and Phalatrikadi Kwatha in Amlapitha– A Randomised Comparative Clinical Study. International Journal of Ayurveda and Pharma Research. 2020;8(11):24-28.

**Source of support:** Nil, **Conflict of interest:** None Declared

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