The comparative and clinical study on Khandamalki and Patoladi Kwatha in Amlapitta W.S.R to “Amlapittai Pryoktavya Kapha pittaha rovidhi”

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Abstract

Amlapitta is one among the commonest disorders prevalent in the society nowadays due to indulgence in incompatible food habits and activities. It is a very common disease affecting mostly the adults. Acharya Vrinda in Vrind Madhav has mentioned the treatment of Amlapitta mainly depends upon Kaphapittaharovidhi. So the present study was planned to prove this principle. Khandamalki and Patoladi Kwatha, very simple, safe and cost effective drugs, have been chosen to explore the efficacy in the management of Amlapitta as Shaman therapy. Shodhan therapy is time consuming and not possible to execute in all the patients so the present study has been carried out to evaluate the Shamana effect of Khandamalki and Patoladi Kwatha. The results of the study are discussed in this paper.

Key words: Amlapitta, Khandamalki, Patoladi Kwatha.

Introduction

Ayurveda is a holistic way of living in which the mind, body, diet and exercise act together to contribute to one’s health. Any vitiation leads to imbalance which needs to be corrected through regulation of diet, exercises, mind and bodily functions. In recent years, health levels are decreasing due to changing of life style, diet pattern, behavioral pattern and mental stress and strain. Everyone is prone to various disease due to the against of our normal physiology of digestion. There have been extraordinary increases disorders incidences related to Annavaahastrotas (Gastrointestinal system) related disorders. Amlapitta is such type of G.I. disorder which is the outcome of faulty dietetic habits, with disturbed function of Agni (digestive fire) is the valuable topic of concern in the present era. Kashyapasamhita was the first text that gave a detailed description of Amlapitta (Kashyap Samhita). Kashyapasamhita has accepted the involvemnt of all three doshas in amlapitta whereas charakasamhita and madhavakara has accepted the dominance of pitta dosha in this disease. The word amlapitta is comprised of two words amla and pitta. The term amla refers to a particular type of taste equated with sour taste which causes excessive salivary secretions. Pitta is a bodily chemical substance which is mainly responsible for the maintenance of the process of digestion and transformation. Amlapitta is a pathological condition in which there is vitiation of pitta dosha in the body pittdosha possesses katu rasa, but after it gets vitiated the katu rasa of pitta dosha changes to amla rasa (Kashyap Samhita).

Aims and objectives

The Comparative and Clinical Study on Khandamalki and Patoladi Kwatha in Amlapitta W.S.R to “Amlapittai Pryoktavya Kaphapittaharovidhi” was undertaken with the following aims and objectives

1. Conceptual study on Amlapitta
2. To evaluate the efficacy of Khandamalki in the management of Amlapitta.
3. To evaluate the efficacy of Patoladi Kwatha in the management of Amlapitta.
4. To evaluate the combined efficacy of Khandamalki and Patoladi Kwatha in the management of Amlapitta.
Materials and Methods

Following materials and methods were adopted for the completion of present research project:

Design of study: Simple, randomized, opens three group comparative studies.

Selection of cases: For clinical study, patients of Amlapitta fulfilling the diagnostic criteria were registered from the OPD/IPD of National Institute of Ayurveda, Jaipur (Agnivesha Charaka Samhita). Diagnostic criteria were mainly based on the signs and symptoms of Amlapitta described in Ayurvedic classics. They include Avipaka, Klama, Utklesha, Tikt-Amlodgara, Hrita-Kanthadaha, AruchiGaurav, Chhardi, Shira-shul.

(a) Inclusion Criteria
i. Patient willing to undergo trial and ready to give written consent.
ii. Age: 16-60 years
iii. Sex- either sex.
iv. Patients presenting with classical features of Amlapitta.

(b) Exclusion Criteria
i. Patients not willing for trial.
ii. Patients below the age of 16 years and above 60 years.
iii. Chronicity more than 5 years.
iv. Patients having organic disease like gastric ulcer, duodenal ulcer etc.
v. Patients suffering from Amlapitta with any other chronic diseases like Asthma, Malignancies, Liver Cirrhosis, and Chronic renal failure, diabetes were excluded from the study.

Research protocol

Administration of drugs

For the present clinical study, 45 patients were enrolled and they were randomly divided into following three groups:-

GROUP A: 15 clinically diagnosed patients of Amlapitta were administered “Khandamalki” 5 gram twice in a day with milk for 30 days.

GROUP B: 15 clinically diagnosed patients of Amlapitta were administered “Patoladikwatha” 20 ml twice in a day (before meal) with honey for 30 days.

GROUP C: 15 clinically diagnosed patients of Amlapitta were administered “Khandamalki” 5 gram twice in a day with milk for 30 days and “Patoladikwatha” 20 ml twice in a day (before meal) with honey for 30 days.

TRIAL DRUGS

GROUP A
DRUG-khandamalki
Dose- 5 gram twice daily
Time of administration- after meal
Duration- 30 days
Anupana- milk

GROUP B
Drug -PatoladiKwatha
Dose- 20 gram twice daily
Time of administration- before meal
Duration- 30 days
Anupana- Honey

GROUP C
Drug -Khandamalki +PatoladiKwatha both

Pathological investigations

Routine hematological, urinary examinations were done before and after treatment to rule out any other pathology.

Drugs

1. Khandamalki
Pharmacodynamic properties of Khandamalki (B.R. Shuladhi karshloka 228-32)

2. PatoladiKwatha
Pharmacodynamic properties of PatoladiKwatha (Amlapitta Nidana Chikitsa Prakrana Shloka 26)
### Table 1.

| SN | Drug       | Botanical name     | Rasa  | Guna   | Veerya | Vipaka       | Karma                        |
|----|------------|--------------------|-------|--------|--------|--------------|------------------------------|
| 1  | Kashmanda  | BeninkasaHispida   | Madhura | Laghu, snigdha | Sheeta | Madhura | Vata-pitta shamak, tridoshahar |
| 2  | Amalaki    | Emblicaofficinalis | Pancharasa | Guru, ruksa | Sheeta | Madhura | Pitta shamak                   |
| 3  | Pipali     | Piper longum       | Katu   | Laghu, snigdha | Amanashsheeta | Madhura | Kapha-vatashamak               |
| 4  | Jiraka     | Cuminumcyminum     | Katu   | Laghu, ruksa | Ushna  | Katu      | Kapha-vatashamak               |
| 5  | Shunti     | Zingiberofficinale | Katu   | Laghu, snigdha | Ushna  | Madhura | Kapha-vatashamak               |
| 6  | Marich     | Piprenigrum        | Katu   | Laghu, tikshna | Ushna  | Katu      | Kapha-Vatashamak               |
| 7  | Talish-patra | Abieswebbiana    | Tikta  | Laghu-tikshana | Ushna  | Katu      | Kapha-Vatashamak               |
| 8  | Dhoyak     | Coriandrum sativum | Tikta  | Laghu-snigdha | Ushna  | Madhura | Pitta-Shamak, Tridoshhar       |
| 9  | Dal-chini  | Cinnamonmzeylanicum | Katu- tikt | Laghu, ruksa | Ushna  | Katu      | Kapha-Vatashamak, Pitta Vardhak |
| 10 | Tej-patra  | Cinnamemumtamala  | Katu- tikt | Laghu, ruksa | Ushna  | Katu      | Kapha-Vatashamak, Pitta Vardhak |
| 11 | Suksha-ela | Elettaria cardamomum | Katu- madhura | Laghu, ruksa | Ushna  | Madhura | Tridoshahar                   |
| 12 | Nagkesar  | Mesuaferrea        | Tikta- kshya | Laghu, ruksa | Ushna  | Katu      | Kaphapittashamak               |
| 13 | Mustak    | Cyperus rotundus   | Tikta, katu, kshya | Laghu, ruksa | Ushna  | Katu      | Kapha-pitta shamak           |
| 14 | Madhu     | Honey              | madhura | Guru, ruksa | Sheeta  | Katu      | Kapha pitta shamak            |
| 15 | Ghrit     | Ghee               | madhura | Guru, snigdha | Sheeta  | Madhura | Pitta shamak                   |
| 16 | Khand     | -                  | madhura | Snigdha, sheeta | Sheeta  | Madhura | Pitta shamak                   |

### Table 2.

| SN | Drug       | Botanical name          | Rasa | Guna   | Veerya | Vipaka       | Karma                        |
|----|------------|-------------------------|------|--------|--------|--------------|------------------------------|
| 1  | Patola     | Trichosanthes dioica    | Tikta | Laghu, Ruksa | Katu  | Ushna      | Kaphapittashamak             |
| 2  | Amalaki    | Emblicaofficinalis      | Pancha rasa | Guru, ruksa | Sheeta | Madhura | Pitta shamak                   |
| 3  | Haritaki   | Ternamalia Chebula      | Pancharasa | Laghu, ruksa | Ushna  | Madhura | Tridosharamainly vatashamak   |
| 4  | Vibhitak   | Ternamali bellirica     | Kashya | Ruksha, laghu | Ushna  | Madhura | Kaphapittashamak             |
| 5  | Nimba      | Azadiracta indica       | Tikta, kshya | Laghu   | shearita  | Katu      | Kaphapittashamak             |
| 6  | Madhu      | Honey                   | Madhura | Guru, ruksa | Sheeta  | Katu      | Kapha pitta shamak            |

### Criteria of assessment-

Scoring system was adopted for assessment of various subjective features and grades from zero to four were accorded to various features according to the severity. The symptoms were evaluated and response of drug was recorded in term of percentage relief of symptoms. Patients were grouped under following categories on the basis of their results of the clinical trial.

- Completely relieved -100% relief from symptoms
- Marked improvement-75-99% relief from symptoms
- Moderate improvement-50-74% relief from symptoms
- Mild improvement-25-50% relief from symptoms
- No improvement-below 25% or no relief

### Statistical evaluation and result analysis

The entire data generated from clinical study was statistically analyzed. The results were made on the basis of grades of various variables compared between pre-trial and post-trial values in terms of percentage, based on mathematical means and its difference. Values between variables were compared with Wilcoxon Signed Ranks Test for dependent samples by using the degree of freedom p value. Intergroup comparison was also done with Kruskal-Wallis Test (Nonparametric ANOVA) and Dunn's Multiple Comparisons Test. The results were expressed in terms of mean, standard deviation (SD) and standard error (SE).

- **P < 0.001** - highly significant
- **P < 0.01** - significant
- **P > 0.05** - non significant
Results and Discussion

Table 1 Effect of therapy on assessment criteria in group A

| Symptoms      | N^1 | Mean Relief | S.D. | S.E. | W & T^2 | P^8 | Results |
|---------------|-----|-------------|------|------|---------|-----|---------|
| Avipaka       | 11  | 1.80±0.93   | 0.86 | 48.14| 0.639   | 0.165 | 6.500   | .0005 HS |
| Klama         | 11  | 1.46±1.20   | 0.26 | 18.18| 0.457   | 0.118 | 2.256   | .0625 NS  |
| Utklesha      | 12  | 2.00±1.33   | 0.67 | 33.33| 0.488   | 0.126 | 5.292   | .0020 HS  |
| TikTamlodgara | 15  | 2.53±1.60   | 0.93 | 36.84| 0.798   | 0.206 | 4.525   | .0010 HS  |
| Daha          | 15  | 2.13±1.46   | 0.66 | 31.25| 0.617   | 0.159 | 4.183   | .0020 HS  |
| Chhardi       | 10  | 1.40±0.86   | 0.53 | 38.09| 0.743   | 0.191 | 2.779   | .0313 S   |
| Shira-shul    | 06  | 0.60±0.26   | 0.33 | 55.55| 0.488   | 0.126 | 2.646   | .0625 NS  |
| Gaurav        | 12  | 1.80±0.93   | 0.86 | 48.14| 0.639   | 0.165 | 6.500   | .0005 HS  |

[1No. of patients having symptoms, 2Mean score before treatment, 3Mean score after treatment, 4Difference in mean, 5Standard deviation, 6Standard error, 7Wilcoxon Signed, 8Degree of freedom]

After analysis of above data of group A, it was observed that the maximum relief in percentage was in shira-shul (55.55%), then in Gaurav (50.00%), then in Aruchi and Avipaka (48.14%), then in Chhardi (38.09%), then in TikTamlodgara (36.84%) , then in Daha (31.25%) and minimum relief in percentage was in Klama (18.18%). According to statistical analysis, Avipaka, Utklesha, TikTamlodgara,Daha, Aruchi shows highly significant result.Chhardi and Gaurav show significant result, whereas Klama and Shira-shul show insignificant result (Agnivesha Charaka Samhita). After analysis of above data of group B, it was observed that the maximum relief in percentage was in Chhardi and Shira-shul (66.66%), then in Avipaka (57.69%), then in Aruchi (52.38%), then in Gaurav (50%), then in Daha (46.42%) , then in Utklesha (34.28%), then in TikTamlodgara (31.42%) and minimum relief in percentage was in Klama (20%). According to
statistical analysis, Avipaka, Utklesha, TiktAmlodgara, Daha, Chhardi and Aruchi shows highly significant result, Gaurav show significant result, whereas Klama and Shira-shul show insignificant result.

Table 3. Effect of therapy on assessment criteria in group C

| Symptoms     | N1 | Mean Relief | S.D.5 | S.E.6 | W & T² | P8   | Results |
|--------------|----|-------------|-------|-------|--------|------|---------|
|              |    | %           | ±     | ±     |        | ±    |         |
| Avipaka      | 14 | 2.46        | 0.73  | 1.73  | 70.27  | 0.248| 6.985   | .0001  | HS     |
| Klama        | 08 | 1.53        | 0.80  | 0.73  | 47.82  | 0.593| 4.785   | .0020  | HS     |
| Utklesha     | 13 | 2.20        | 1.20  | 1.00  | 45.45  | 0.645| 5.916   | .0005  | HS     |
| TiktAmlodgara| 15 | 2.53        | 0.93  | 1.60  | 63.15  | 0.828| 7.483   | .0002  | HS     |
| Daha         | 15 | 2.33        | 0.93  | 1.40  | 60.00  | 0.632| 5.73    | .0010  | HS     |
| Chhardi      | 07 | 2.00        | 0.73  | 1.26  | 63.33  | 0.883| 5.551   | .0010  | HS     |
| Shira-shul   | 11 | 1.66        | 0.33  | 1.33  | 80.00  | 0.975| 5.292   | .0010  | HS     |
| Gaurav       | 09 | 1.46        | 0.40  | 1.06  | 72.72  | 0.961| 4.298   | .0039  | HS     |
| Aruchi       | 13 | 2.00        | 0.40  | 1.60  | 80.00  | 0.828| 8.411   | .0001  | HS     |

1No. of patients having symptoms, 2Mean score before treatment, 3Mean score after treatment, 4Difference in mean, 5Standard deviation, 6Standard error, 7Wilcoxon Signed, 8Degree of freedom

After analysis of above data of group C, it was observed that the maximum relief in percentage was in Shira-shul and Aruchi (80%), then in Gaurav (72.72%), then in Avipaka (70.27%), then in Utklesha (45.45%). According to statistical analysis, Avipaka, Klama, Utklesha, TiktAmlodgara, Daha, Chhardi, Shira-shul, Gaurav and Aruchi shows highly significant result.

Fig 3.
### Table 4 – Intergroup comparison by Kruskal-Wallis Test (Nonparametric ANOVA)

| S.No. | Symptoms     | KW Value | P Value | Results |
|-------|--------------|----------|---------|---------|
| 1.    | Avipaka      | 7.582    | P<0.05  | S       |
| 2.    | Klama        | 7.013    | P<0.05  | S       |
| 3.    | Utklesha     | 6.132    | P<0.05  | S       |
| 4.    | TiktAmlodgara| 9.107    | P<0.05  | S       |
| 5.    | Daha         | 11.092   | P<0.01  | HS      |
| 6.    | Chhardi      | 6.339    | P<0.05  | S       |
| 7.    | Shira-shul   | 11.015   | P<0.01  | HS      |
| 8.    | Gaurav       | 0.667    | P<0.05  | S       |
| 9.    | Aruchi       | 9.833    | P<0.01  | S       |

### Table 5 Dunn's Multiple Comparisons Test

| S.No. | Symptoms     | Dunn's Multiple Comparisons Test | Mean Rank Difference | P Value | Remarks |
|-------|--------------|----------------------------------|----------------------|---------|---------|
| 1.    | Avipaka      | Group A & Group B                | -1.76                | P>0.05  | NS      |
|       |              | Group A & Group C                | -11.63               | P<0.05  | S       |
|       |              | Group B & Group C                | -9.86                | P>0.05  | NS      |
| 2.    | Klama        | Group A & Group B                | -0.00                | P>0.05  | NS      |
|       |              | Group A & Group C                | -9.40                | P>0.05  | NS      |
|       |              | Group B & Group C                | -9.40                | P>0.05  | NS      |
| 3.    | Utklesha     | Group A & Group B                | -2.33                | P>0.05  | NS      |
|       |              | Group A & Group C                | -10.16               | P>0.05  | NS      |
|       |              | Group B & Group C                | -7.83                | P>0.05  | NS      |
| 4.    | TiktAmlodgara| Group A & Group B                | 2.53                 | P>0.05  | NS      |
|       |              | Group A & Group C                | -10.33               | P>0.05  | NS      |
|       |              | Group B & Group C                | -12.86               | P>0.05  | S       |
| 5.    | Daha         | Group A & Group B                | -3.73                | P>0.05  | NS      |
|       |              | Group A & Group C                | -13.36               | P<0.01  | HS      |
|       |              | Group B & Group C                | -9.63                | P>0.05  | NS      |
| 6.    | Chhardi      | Group A & Group B                | -4.73                | P>0.05  | NS      |
|       |              | Group A & Group C                | -11.26               | P<0.05  | S       |
|       |              | Group B & Group C                | -6.53                | P>0.05  | NS      |
| 7.    | Shira-shul   | Group A & Group B                | -0.66                | P>0.05  | NS      |
|       |              | Group A & Group C                | -12.83               | P<0.01  | HS      |
|       |              | Group B & Group C                | -12.16               | P<0.05  | S       |
| 8.    | Gaurav       | Group A & Group B                | -3.80                | P>0.05  | NS      |
|       |              | Group A & Group C                | -11.00               | P<0.05  | S       |
|       |              | Group B & Group C                | -7.20                | P>0.05  | NS      |
| 9.    | Aruchi       | Group A & Group B                | 2.06                 | P>0.05  | NS      |
|       |              | Group A & Group C                | -11.06               | P<0.05  | S       |
|       |              | Group B & Group C                | -13.13               | P<0.05  | S       |
Overall assessment of therapy

At the end of treatment each patient result were carefully observed to assess the overall effect of therapy.

| Grading       | Group A | Group B | Group C |
|---------------|---------|---------|---------|
| Complete relief | 0 %    | 0 %     | 0 %     |
| Marked relief  | 0 %    | 0 %     | 26.66%  |
| Moderate relief| 20 %   | 46.67%  | 60.00%  |
| Mild relief    | 53.33% | 53.33%  | 6.67%   |
| No relief      | 26.67% | 0 %     | 6.67%   |

In group A, 26.67% patients achieved no relief, 53.33% patients achieved mild relief, 20% patients achieved moderate relief, no any patients achieved marked and complete relief.

In group B, 53.33% patients achieved mild relief, 46.67% patients achieved moderate relief, and no any patients achieved marked and complete relief.

In group C, 06.67% patients achieved no relief, 06.67% patients achieved mild relief, 60% patients achieved moderate relief, 26.66% patients achieved marked relief and no any patients achieved complete relief.

Fig 4.

Degradation by pathogenesis by formulated drugs-

Drugs which is Agnideepaka, Kaphashamaka antagonist properties of VidagdhaPitta, Srotoshodhaka and Vatamalomaka is useful as palliative treatment of Amlapitta (Sushruta Sushruta Samhita). In Group A, with Anupana of lake warm milk was given. Main ingredients of Khandamalaki, Kushmanda and Amalaki. The properties of Kushmanda are Laghu, Snigdhga, SheetaVirya, MadhuraRasa and Vipaka. Due to its properties it suppresses Ushna and Tikshna properties of Vidagdhipitta. Amlaki is AmlaRasadominant Pancharasa, SheetaVeerya and MadhuraRasa and Vipaka. Due to its properties it digests the AmaRasa. Ruksha, Laghu, UshanaVirya and Katu, TiktaRasa. All of these drugs digest the SamAnsha of AmaRasa. There is a lot of importance of Anupana in increasing the activity of drug. There is Anupana of cow’s milk which is also SheetaVirya and MadhuraRasa dominate and suppress the excess quantity of Pitta in Amlapitta. Mishris also Pittashamak due to MadhuraRasa. Medhya effect of Kushmanda prevents its etiology due to psychological factor like Klam, Anidra etc.

PatoladiKwatha was given in group ‘B’ with Prakshap of Madhu. Ingredients of PatoladiKwatha are mostly Ruksha, Laghu, Tikt, Kasaya, AnushnaSheetaVeerya, MadhuraVipaka. Ruksha, Laghu properties and TiktaRasa dominant Dravya absorbs the Dravansha (liquid) of VidgadhaPachakaPitta. In formulated drug Kashaya rasa dominant Dravyas are Haritaka, Vibhakti and Nimba. TiktaKashyaRasas are Kaphapittashamak.
Triphala is mild laxative and Anulomma due to its Prabhava. Madhu as a PrakshepDravya, due to SheetAvirya, Ruksha, Kashaya and MaduraRasa is also Kaphapittashamak. Due to Sandhanya property of Madhu it is also effective in complication of Amlapitta like gastric ulcer etc. by the analysis of ingredients of Patoladikwatha it is found that most of its ingredients are Kaphapittashamak which is just antagonistic of causative factors of Amlapitta and increasing the Agni. Due to increase in Agni proper digestion of Ahara will be possible and NiramaPitta will be produced not VidgdhaPitta. As a result of it AmalpittaVyadhi will not be produced.

Conclusion
Clinical study reveals that both drugs Khandamalki and PatoladiKwatha showed highly significant results. In group C the results were better than group A & B. Because the combination of both drugs had been proved more effective in patients than single one. Hence, it can be concluded that the Amlapitta is better managed by administration of both drug without any side effect and “Kaphapittaharovidhi” is beneficial in the management of Amlapitta disease.

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