Clinical Study on the Effectiveness Of Pippali Khanda in the Management of Amlapittta

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Abstract

Background: Amlapitta(Acid peptic disorder) is disease of the Annavaha Srotas (gastrointestinal tract) which results primarily because of indulgence in Ahita Ahara Vihara Sevana (irregular dietary habit and day to day activity). Khanda (sugar granules) is widely acceptable dosage forms in the present scenario due its palatability, shelf life and easy administration. The selected drug Pippali Khandapossesses Deepana (enhances digestion), Pachana (digestive) and Vatanulomana (regulates Vata). Study has been undertaken to evaluate the effectiveness of Pippali Khanda in the management of Urdhvaga Amlapitta having dominance of Kapha and Pitta Dosha. Methods: Among the 32 registered patients 30 of them completed the course of treatment. Pippali Khanda was administered in a dose of three gram twice daily, fifteen minutes after food, for fifteen days. Patients were assessed before, end of first week and 15th day of treatment. For statistical analysis, ordinal data were assessed by Friedman's test and Wilcoxon signed rank as Post Hoc after applying Bonferroni correction. Results: There were statistically highly significant improvements in the signs and symptoms of Amlapitta. (p<0.05) observed. Conclusion: Pippali Khanda is effective and useful in the management of signs and symptoms of Amlapitta besides improved the parameters of Agni and digestion.

Keywords: Ayurveda, acid peptic disorder, Amlapitta, Pippali Khanda, Agni.

Introduction

Amlapitta (acid peptic disorder) is one of the commonest Annavaha Srotas Vyadhi (gastrointestinal tract disorder) (1). When any of causative / triggering factors causes Mandagni (reduced digestive power), it leads to undigested food particles (Vidagdhajirna) manifesting as Amlapitta (2). Amlapitta is a condition where sour nature (Amla Guna) of Pachaka Pitta aggravates due to Shukttata of the undigested food (Anna) leading to burning sensation (Vidaha). Hence, Amlapitta being Pitta-Kapha Pradhana Tridosha Vyadhi, respective Lakshana of involved Dosha will be seen according to variation of involved Dosha.

In the management of Amlapitta, Vamana (emasis) or Virechana (purgation) are the main line of Shodhana (detoxification) and followed by this, Langhana (fasting), Laghu Bhojana (light digestive food) and Agnideepana (enhances digestion) measures to adopt (3). A population-based study, using a validated questionnaire, found that 58.7% of the population has heartburn or acid regurgitation at least once during the course of a year and that 19.8% experience symptoms at least once weekly. It is estimated that approximately 50% of patients with typical reflux symptoms have erosive oesophagitis.

Pippali Khanda is Katu (pungent), Madhura (sweet), Tikta (bitter) in Rasa, Laghu (lightness) Ruksha (dry) in Guna, Veerya is Sheeta (cold), Vipakais Madhura (sweet) and Doshagnatha is Pitta Kaphahara. Pippali is the best medicine for Amapachana and alleviates the Srotasrodha by Laghu Tikshna Guna. Hence drug was selected.

Objective

- The study was conducted to assess clinical effectiveness of Pippali Khanda in the management of Urdhvaga Amlapitta.

Methodology

Source of data:

Patients were recruited from outpatient and inpatient unit of Siddhakala College of Ayurveda.

Methods of collection of data:

Patients were screened and selected based on the screening form. A case report form was prepared with all points of history taking, physical signs and symptoms of Urdhvaga Amlapitta. The selected patients were subjected to detail clinical history and complete physical examination before undergoing
the clinical study. Institutional ethics clearance was obtained from Institutional Ethics Committee, Sri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Hassan (SDM/ICE/45/2014-2015 dated 01-04-2015) and study was registered in Clinical Trials Registry of India (CTRI/2016/05/006918).

**Diagnostic criteria:**
Diagnosis was made on the basis of Samanya Lakshanas of Urdhwa Amlapitta viz. Hrullasa(nausea), Mandagni (reduced digestive power), Chardi(vomiting), Kaphanishteevan (excessive salivation), Bhuktevigdagdha (burning sensation after food intake), Utklesha (sour belching), Tikta- Amla Udgahra (bittersour belching), Klama (triedness), Gaurava (heaviness), Hrit- Kantadaha (burning sensation of throat and chest region), Analasada (reduced food intake)and Aruchi (lack of taste) (4).

**Inclusion Criteria:**
Patients with chronicity upto 5 years between age group of 18-55 years of either gender, irrespective of socio-economic status and those who are ready to sign the informed consent form were included.

**Exclusion criteria:**
Patients with history of systemic illness namely diabetic mellitus and hypertension, thyroid disorders, cardiac pathology, immunodeficiency disorders like AIDS, Parinama Shula (gastric ulcer, duodenal ulcer), Annadrava Shula, Krimiroga(worms manifestation) and Arbuda (tumour), hematemesis, melena and anaemia, drug, alcohol and tobacco induced Amlapitta were excluded. Routine laboratory investigations were performed to rule out any major pathology.

**Intervention:**
The trial drug PippaliKhanda (5) is taken from AmlapittaAdhikaarof BhaishajyaRatnavali for the management of Urdhva Amlapitta.

| Table 1: list of ingredients, Latin names, part used and quantity of PippaliKhanda |
|------------------|-----------------|-----------------|---------------|
| Sl. No. | Sanskrit Name | Botanical name | Part used | Proporti on |
| 1 | Pippali | Piper longum | Dried rhizome | 15 parts |
| 2 | Satavari | Asparagus racemosus | Decoction | 32 parts |
| 3 | Amalaki | Emblicaofficinalis | Fruit | 1 part |
| 4 | Dhanyaka | Coriander sativum | Fruit | 1 part |
| 5 | Krishnajiraka | Carumbulbacastanum | Seed | 1 part |
| 6 | Twak | Cinnamomumzeylanicum | Bark | 1part |
| 7 | Ela | Elettariacardamomum | Seed | 1part |
| 8 | Tejapatra | Cinnamomumtamala | Leaf | 1part |
| 9 | Mustaka | Cyperusrotundus | Tuber | 1part |
| 1 | Swetajiraka | Cuminacuminum | Seed | 1part |
| 1 | Shunti | Zingiberofficinale | Dried rhizome | 1part |
| 1 | Vansalocha | Bambusaarundinaceae | - | 1part |
| 1 | Hariati | Terminaliachebula | Fruit rind | 1part |
| 1 | Khadir | Acacia catechu | Sara | 1/2 part |
| 1 | Maricha | Piper nigrum | Fruit | 1/2 part |
| 1 | Ghrita | - | - | 23 parts |
| 1 | Goksheera | (Cow milk) | - | 125 parts |
| 1 | Madhu | (Honey) | - | 12 parts |
| 1 | Mishri | (Sugar) | - | 70 parts |

**Method of Preparation of PippaliKhanda:**
Ksheera (milk) was boiled with Pippalichurna (powder) on mriduagni. When paste was formed than, it was mixed with Go ghrita, Satavarikkatha (decoction) and sugar, fried on mridhuagni until Ghrita got separated from the paste form. When PakaLakshanas were obtained, vessel taken out of the fire and SukshmaChurna (fine powder) of Prakshepa drugs was added and mixed uniformly. After it gets cooled, Madhu (honey) was added to it. (6)

**Packing:**
Prepared drug was packed in airtight bottle, properly labelled and weighted 100 gm.

**Dosage:**
3 gm twice daily

**Duration:**
15 days

**Anupana:**
Normal water and milk (7)
Pathyapthya:
For diet list of included items are as follow old rice, barley, wheat, mudga, cool boiled water, sugar, honey, well ripened fruit of white gourd (kusmanda), pomegranate (dadima), gooseberry (Amalaki) and all bitter juices should be used. Spicy food item should be avoided along with oily and fried items.

Assessment Criteria
The effect of therapy was assessed on the basis of changes in signs and symptoms of UrdhvaAmlapitta using questionnaire that was developed for the study. Patients were assessed at three intervals i.e. before, end of first of week and 15th day of treatment. These were assessed by giving specific scores which were helpful in Statistical analysis. These scores are presented as follows.

Do you have vomiting sensation (Hrullasa)
0 – No
1 – Very less
2 – Sometime
3 - Always

Do you have appetite (Aruchi)
0 – No
1 – Very less
2 – Sometime
3 – Always

Do you have feeling of indigestion (Mandagani)
0 – No
1 – Very less
2 – Sometime
3 – Always

Do you have Vomiting before and after food intake (Chardi)
0 – No
1 – Very less
2 – Sometime
3 – Always

Increased frequency of sputum (Kaphanishteevan )
0 – No
1 – Very less
2 – Sometime
3 – Always

Increased frequency of sour belching (Tiktamlodgara)
0 – No
1 – Very less
2 – Sometime

Burning sensation of chest, throat and stomach region after taking food (Bhuktevidagdha)
0 – No
1 – Very less
2 – Sometime
3 - Always

Burning sensation of chest, throat and stomach region (Hrith- kantadaha)
0 – No
1 – Very less
2 – Sometime
3– Always

Weakness effecting day to day activity (Analasada)
0 – No
1 – Very less
2 – Sometime
3 - Always

Bitter taste of mouth. (Tiktsayta)
0 – No
1 – Very less
2 – Sometime
3 – Always

Tongue coating present (Jihwalipta)
0 – No
1 – Very less
2 – Sometime
3 – Always

Do you have headache (Shirashoola)
0 – No
1 – Very less
2 – Sometime
3 – Always

Do you have heaviness of body (ShareeraGaurava)
0 – No
1 – Very less
2 – Sometime
3 – Always

Do you have feeling of tiredness present (Klama)
0 – No
1 – Very less
2 – Sometime
3 – Always
Observation

In this study among 32 patients 30 completed the whole treatment course, as 2 patients left the treatment due to their personal problems.

Table 2: Demographic Profile of patients

<table>
<thead>
<tr>
<th>Geographic observation</th>
<th>Predominance</th>
<th>Precentage</th>
<th>No of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (range 18-55yrs)</td>
<td>28-37 years</td>
<td>53.1%</td>
<td>17</td>
</tr>
<tr>
<td>Gender</td>
<td>Equally distributed(male and female)</td>
<td>50.0%</td>
<td>16</td>
</tr>
<tr>
<td>Marital status</td>
<td>Married</td>
<td>87.5%</td>
<td>28</td>
</tr>
<tr>
<td>Socio-economic status</td>
<td>Upper middle class</td>
<td>62.5%</td>
<td>20</td>
</tr>
<tr>
<td>Education status</td>
<td>Graduate</td>
<td>46.9%</td>
<td>15</td>
</tr>
<tr>
<td>Chronicity</td>
<td>More than 3 months</td>
<td>50.0%</td>
<td>16</td>
</tr>
<tr>
<td>Occupation</td>
<td>Profession</td>
<td>40.6%</td>
<td>13</td>
</tr>
<tr>
<td>Nature of work</td>
<td>Standing</td>
<td>65.6%</td>
<td>21</td>
</tr>
<tr>
<td>Working environment</td>
<td>Equally distributed (Stressful and comfortable)</td>
<td>50.0%</td>
<td>16</td>
</tr>
<tr>
<td>Diet</td>
<td>Mixed</td>
<td>87.5%</td>
<td>28</td>
</tr>
<tr>
<td>Dietary Habits</td>
<td>Vishamashana</td>
<td>65.6%</td>
<td>21</td>
</tr>
<tr>
<td>Agni</td>
<td>Manda</td>
<td>62.5%</td>
<td>20</td>
</tr>
<tr>
<td>Koshtha</td>
<td>Madhya</td>
<td>78.1%</td>
<td>25</td>
</tr>
</tbody>
</table>

Results

Friedman’s test (p<0.05) was applied to assess the significant change in the symptoms having ordinal data followed by Post hoc analysis with Wilcoxon signed rank tests was conducted with a Bonferroni correction applied, resulting in a significant level of P<0.017 to interpret the time of significant change. (Table 3)

Discussion

‘Amlapitta’ is a combination of two words Amla and Pitta. Among these two words the Amla denoted the Rasa (sour taste) and the Pitta denotes the Dosha involved in this disease. The Pitta Dosha is bestowed with the function of digestion and metabolism.

The overview of the ingredients of the drug suggests that dominant Rasa of the Combination in whole turns out to be Katu-Madhura Rasa followed by Tikta-Kashaya Rasa. All these three Rasas are Kapha-Pitta Hara in nature. Mainly Katu-Tikta Rasa is Kapha Hara, Tikta-Madhura is Pitta Dosha Hara,
Where as Kashaya is acting on both Kapha and Pitta. By this we can conclude that PippaliKhanda has the action of Agni Deepana, AmaPachana, Vatanulomana, Dahaprasamana (reduce burning sensation) and Trishnanigrahana (reduced thirst).

Majority of parameters found statistically significant improvement at the level of P < 0.001 (by Friedman test and post hoc Wilcoxon test analysis). All symptoms recorded at 3 intervals i.e. baseline, on 7th day and on 15th day.

**Effect of PippaliKhanda on parameter**

### Table 4: Effect of Pippali Khanda on Parameters of Urdhava Amlapitta

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reduction on 7th day</th>
<th>Reduction on 15th day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No of patients (%)</td>
<td>No of patients (%)</td>
</tr>
<tr>
<td>Hrullasa</td>
<td>15 (60.0%)</td>
<td>11 (44.0%)</td>
</tr>
<tr>
<td>Mandagni</td>
<td>12 (50.0%)</td>
<td>12 (50.0%)</td>
</tr>
<tr>
<td>Aruchi</td>
<td>8 (53.3%)</td>
<td>9 (60.0%)</td>
</tr>
<tr>
<td>Chardi</td>
<td>4 (22.2%)</td>
<td>12 (66.6%)</td>
</tr>
<tr>
<td>Kaphanishteevan</td>
<td>4 (36.3%)</td>
<td>5 (45.5%)</td>
</tr>
<tr>
<td>Tiktamlodagara</td>
<td>19 (61.2%)</td>
<td>20 (64.5%)</td>
</tr>
<tr>
<td>Bhuktevidagdha</td>
<td>10 (62.5%)</td>
<td>10 (62.5%)</td>
</tr>
<tr>
<td>Utklesha</td>
<td>3 (30.0%)</td>
<td>5 (50.0%)</td>
</tr>
<tr>
<td>Hrit-KantaDaha</td>
<td>19 (59.3%)</td>
<td>19 (59.3%)</td>
</tr>
<tr>
<td>Analasada</td>
<td>10 (71.4%)</td>
<td>8 (57.1%)</td>
</tr>
<tr>
<td>UdaraShoola</td>
<td>11 (50.0%)</td>
<td>12 (54.5%)</td>
</tr>
<tr>
<td>Tiktasyata</td>
<td>4 (30.7%)</td>
<td>8 (61.5%)</td>
</tr>
<tr>
<td>Jihwalipta</td>
<td>11 (42.3%)</td>
<td>15 (57.6%)</td>
</tr>
<tr>
<td>Shirashoola</td>
<td>14 (60.8%)</td>
<td>13 (56.5%)</td>
</tr>
<tr>
<td>ShareeraGaurava</td>
<td>15 (57.6%)</td>
<td>14 (53.8%)</td>
</tr>
<tr>
<td>Klama</td>
<td>18 (64.2%)</td>
<td>18 (64.2%)</td>
</tr>
</tbody>
</table>

On analysis from baseline and 15th day effect, PippaliKhanda significantly reduced Hrullasa in 68. 7% patients, the sensation nausea caused due to the indigested food, VruddhaKapha and Pitta. Second most important symptom, Mandagni caused due to both irregular dietary habit and improper Gati of Vata, PippaliKhanda effectively reduced Mandagni in 65.6% patients.

Chardi is primarily a gastro-intestinal symptom caused due to the stomach trying to empty its undigested or stale food material (Aama) and Vata moving in Pratiloma Gati, being Deepana, Pachana and Amahara nature of drug contributes in reducing Chardi in 59.3% of sufferers.

Ama formation at Agni level cause Aruchi and Jihwalipta simultaneously which is neatly controlled by Tikta-Kashaya Rasa of PippaliKhanda and reduced symptom in 81.2% of effected persons.

Shuktata of the Anna Rasa in time period will attained Shuktata vitiates the Pitta and causes Vidagadhata and Aruchi is maintained with Tridoshahara action of combination, reduces in 88.7% of patients. Pitta Dosha when vitiates has Amla Rasa dominant cause for Utklesha, Tiktamlodagara, Tiktasyata, Hrit-KantaDaha and Analasada, all symptoms showed remarkable improvement. On evaluating Sarvadhahikasymptoms, Dushtiof SamanaVata, Pachaka Pitta and KledakaKapha along with the formation of Ama will give rise to UdaraShoola, same Dosha in later stage manifest into Shirashoola, ShareeraGaurava and Klama. So drug acting at Ama level having Deepana, Pachana property helps to reduces symptoms. PippaliKhanda has the action of Agni Deepana, AmaPachana, Vatanulomana, Dahaprasamana and Trishnanigrahana helps in reducing above symptoms.

**Conclusion**

PippaliKhanda at a dose of 3gm twice daily, 15 minutes after food, orally for 15 days significantly reduced symptoms of Urdhava Amlapitta like Hrullasa, Mandagni, Chardi, Kaphanishteevan, Utklesha, Hrit-kanta Daha, Analasada, UdaraShoola, Tiktasyata and Aruchi. The therapy also significantly improved SarvadhahikaLakshana namely, Klama, Gaurava and Shirashoola. The trial drug dose not manifests any side effects, adverse reaction or untoward events in the patients of UrdhavaAmlapitta.

**References**