Clinical Study

Evaluation of Pippali (Piper longum Linn.) and Lauha Bhasma on blood haemoglobin level

*Dr. Swati Ugale, **Dr. Madhav Borude, ***Dr. Sudipta Kumar Rath

Abstract

Introduction – Haemoglobin (Hb) deficiency is a global public health problem which has social as well as economic consequences. Conventional and even Ayurvedic Iron supplements such as lauha bhasma sometimes fail to give desired results in the management of Hb deficiency. This might be attributed to improper absorption and utilization due to agnimandya or srotoavarodha. This can be well addressed by adding a suitable deepana- srotoshodhana (bioavailability enhancing) drug that can increase iron absorption and utilization. This clinical trial was thus designed to assess the role Pippali plays in enhancing the effect of lauha bhasma on Blood Hb level.

Objectives - To evaluate efficacy of pippali and lauha Bhasma on blood haemoglobin level in adult healthy volunteers.

Material and Method – (i) Design – Open, three arm, randomized and comparative clinical trial (ii) Setting – OPD registered volunteers, Participants – 30 Consenting Healthy volunteers(15-60 years of age), of either sex, having Hb between 7-10 gm% in females and 8-12 gm% in males, Intervention – 3 groups, Group A - Pippali 1gm dry powder b.d. with water after food, Group B - Louha Bhasma 125mg b.d. with water after food and Group C - Pippali 1gm and Louha Bhasma 125mg b.d. with water after food twice a day, Intervention Period - 45 Days, Outcome measures – Blood Hb level.

Results – Significant result in Group A, whereas highly significant results were observed in Group B and Group C. Most effective result - 18.93% improvement in Hb level in Group C as compared to Group A (13.59%) and B (14.20%).

Conclusion – Pippali enhances the efficacy of lauha bhasma in Hb deficiency.

Keywords- Ayurveda, Pippali, Lauha, Bhasma, Haemoglobin, Hb.

Sarasa

पिप्पली - हीमोग्लोबिन (एचबी) की कमी एक वैश्विक सार्वजनिक स्वास्थ्य समस्या है जिसके सामाजिक और आर्थिक परिणाम होते हैं। लोहे भ्रम आयार की आपूर्ति कम है तेलकन कभी कभी एचबी की कमी के चिकित्सा में लोहे भ्रम वृद्धिक परिणाम देने के लिए असफल होता है। इसका कारण लोहे भ्रम का अनुपचारित अवशोषण और उपयोग है, जो अधिग्राभ्यांश या स्वस्थता होने के कारण हो सकता है। इसके समाधान हेतु एक दीपी और स्वस्थता करने वाला (जैव उपलब्धता बढ़ाने वाला) द्रव्य लोहे भ्रम के साथ दिया जा सकता है, जो लोहे के अवशोषण और उपयोग में वृद्धि कर सकता है। अतः इस चिकित्सकीय परीक्षण को हीमोग्लोबिन (एचबी) स्तर पर लोहे भ्रम के प्रभाव को बढ़ाने में पिप्पली की भूमिका का आकलन करने के लिए जड़ाई किया गया था।

उद्देश्य - व्यस्त स्वस्थ स्वस्थ समस्याओं में रक्त में हीमोग्लोबिन स्तर पर पिप्पली और लोहे भ्रम की प्रभावकारिता का मूल्यांकन करने हेतु प्रयोग किया।

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Clinical Study

Evaluation of Pippali (Piper longum Linn.) and Lauha Bhasma on blood haemoglobin level

Dr. Swati Ugale, Dr. Madhav Borude, Dr. Sudipta Kumar Rath

Introduction

Haemoglobin (Hb) deficiency is one of the most important health issues concerning global population. Hb contains almost 65% of the body iron in humans. Therefore iron deficiency is a significant cause for Hb deficiency. In developing countries like India 30-70% of the population is iron deficient. On an average 56% of adolescent girls are anaemic and around 30% of adolescent boys are suffering from anaemia. Nearly 50-80 percent of mothers suffer from anaemia due to iron-deficiency in their diet. Puerperal morbidity is higher among women with Hb level below 6.5g/dl compared to women with normal Haemoglobin level. Anaemia is not confined to pregnant women alone but also has effect on other population in the society. The Hellen Kellar Institute for girls (1996) estimated that 83.9 percent girls of age between 12 and 18 years in rural India were found to be anaemic; the level is high among girls with no schooling (92.7 %). Adolescent girls require continuous replacement of iron during menstruation (Brabin and Brabin, 1992).

Although the aetiology of Iron deficiency Anaemia (IDA) is multifaceted, it generally results when the iron demands by the body are not met by iron absorption, regardless of the reason. Individuals with IDA have inadequate intake, impaired absorption or transport, physiologic losses associated with chronological or reproductive age, or chronic blood loss secondary to disease. In adults, IDA can result in a wide variety of adverse outcomes including diminished work or exercise capacity, impaired thermoregulation, immune dysfunction, GI disturbances, and cognitive impairment.

Usual line of treatment for Hb deficiency is iron supplements. But iron supplements sometimes fail to give desired results and also it has some unwanted effects such as gastrointestinal irritation, nausea, constipation, etc. Ayurvedic texts also have mentioned iron supplements like lauha bhasma and mandura bhasma. But they also fail to increase Hb level in all patients when used as a stand alone drug. This might be attributed to improper absorption and utilization consequent to agnimandya or srotoavarodha. Hence, a suitable drug is needed to be administered which can increase iron absorption and utilization by deepana and srotoshodhana activity (bioavailability enhancers). Pippali (Piper longum) contains 62.8mg/100gm iron (NIN, Hyderabad) and it is also indicated in Pandu roga chikitsa. Yakrit and pliha are moolsthans of raktawaha srotas, which the site of the rakta dhatu formation. Hence it can be deduced that in Hb deficiency there might be pathological changes in yakrit and pliha. Vagbhata has mentioned pippali is the best medicine for the pliharoga. Thus pippali can have a role in Hb deficiency states. Piperine, major chemical constituent of pippali, is the bioavailability enhancer. Pippali enhances absorption of many nutrients. Therefore the present study is planned to see the efficacy of pippali and lauha bhasma on blood haemoglobin level. This clinical trial was thus designed to assess the role Pippali plays in enhancing the effect of lauha bhasma on Blood Hb level.

Aims and Objectives

To evaluate efficacy of pippali and lauha Bhasma on blood haemoglobin level in adult healthy volunteers.

Materials & Methods

Study Design – An open, three arm, randomized and comparative clinical trial was designed to test the hypothesis of the current work.

Study Population – 30 consenting apparently healthy volunteers of 15 – 60 years of either sex were enrolled for this trial after screening them as per the inclusion criteria. Volunteers were randomly divided into 3 groups, each group having 10 volunteers.

Study Setting – Selected volunteers were
registered in the Out Patient Department of National Institute of Ayurveda, Jaipur (N.I.A. OPD) for the clinical trial.

**Study Period** – 12/9/2014 to 27/1/2015

**Volunteers Inclusion criteria**

- Haemoglobin between 7-10 gm% in females and 8-12 gm% in males.

**Volunteers exclusion criteria**

- Pregnant ladies.
- Patients suffering from malignant diseases like leukaemia.
- Patients suffering from serious diseases such as Ischemic heart disease (IHD), congestive cardiac failure (CCF), Diabetes mellitus (DM), renal disorders, acute and chronic blood loss, bleeding disorders, haemoglobinopathies.
- Patients suffering from chronic disorders like Rheumatoid arthritis (RA), hypothyroidism and hyperthyroidism.
- Anaemia due to causes other than iron deficiency.
- Patients that have recently taken iron supplement therapy.

**Volunteers discontinuation/withdrawal criteria**

- Any Adverse/Serious adverse event is encountered, where continuation of study poses medical risk to the Volunteer.
- Volunteers not complying with the protocol.
- Volunteers not turning up for assessment in time.
- Volunteers expressing desire to withdraw.

**Trial Drug** –

API directs that dried fruit of *Piper longum* Linn. is the botanical source of the drug *pippali*. There is no controversy regarding the botanical identification of the *pippali*. Hence in the present study fruits of *Piper longum* Linn. was selected as the trial drug. It was collected by the scholar herself from Kochi, Kerala, after due botanical authentication (Identification no- *Piper longum* Linn.-RUBL211473). Powder was prepared by pulveriser. This powder was passed through sieve size 80. This powder was packed into soft gelatine capsules of 500 mg each.

*Lauha bhasma* was purchased from the GMP certified company named Krishna Gopal Ayurved Bhawan, Kalra. *Lauha bhasma* was packed into soft gelatine capsules of 125 mg each by a capsule filling machine.

Both the drugs were subjected to pharmacognostical and phytochemical investigations for quality assurance and found to be quality drugs for use.

**Dose, Duration & Administration** –

**Group A:** *Piper longum* dry fruit powder – 1 gm, 2 capsules of 500 mg each, with water after food twice a day for 45 days

**Group B:** *Louha Bhasma* - 125 mg, 1 capsule of 125 mg, with water after food twice a day for 45 days

**Group C:** *Piper longum* dry fruit powder – 1gm, 2 capsules of 500 mg each and *Louha Bhasma* - 125 mg, 1 capsule of 125 mg, with water after food twice a day for 45 Days.

**Criteria of Assessment:**

The enrolled volunteers were assessed for Blood Hb % at baseline and after the end of the trial i.e on 46th day.

**Observations**

Blood Hb % of the volunteers were assessed and recorded before and after treatment. The values are given in Table I.
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Table no. I- Observations of the change in Hb%

<table>
<thead>
<tr>
<th>Volunteer</th>
<th>Group A</th>
<th>Volunteer</th>
<th>Group B</th>
<th>Volunteer</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT</td>
<td></td>
<td>BT</td>
<td>AT</td>
</tr>
<tr>
<td>1</td>
<td>10</td>
<td>10.1</td>
<td>1</td>
<td>9.1</td>
<td>11.9</td>
</tr>
<tr>
<td>2</td>
<td>8.6</td>
<td>9.6</td>
<td>2</td>
<td>10</td>
<td>11.3</td>
</tr>
<tr>
<td>3</td>
<td>8.9</td>
<td>12.6</td>
<td>3</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>11.9</td>
<td>11.9</td>
<td>4</td>
<td>10</td>
<td>10.6</td>
</tr>
<tr>
<td>5</td>
<td>10</td>
<td>11.7</td>
<td>5</td>
<td>11.3</td>
<td>11.7</td>
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<td>6</td>
<td>10</td>
<td>10.6</td>
<td>6</td>
<td>10.5</td>
<td>13</td>
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<tr>
<td>7</td>
<td>8.1</td>
<td>11.4</td>
<td>7</td>
<td>8.7</td>
<td>11.9</td>
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<td>8</td>
<td>11.4</td>
<td>12.4</td>
<td>8</td>
<td>10</td>
<td>11.4</td>
</tr>
<tr>
<td>9</td>
<td>10.4</td>
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<td>9</td>
<td>10.8</td>
<td>11</td>
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<tr>
<td>10</td>
<td>8.7</td>
<td>9</td>
<td>10</td>
<td>8.8</td>
<td>9</td>
</tr>
</tbody>
</table>

BT – Before Treatment, AT – After Treatment

Results- The recorded values were subjected to statistical analysis for their significance and results. Statistical analysis was conducted by Graph pad prism-6 software. For obtaining results in individual group (before and after treatment) paired ‘t’ test was applied while for intergroup comparison ANOVA test was applied. Obtained results are given in Table II and Table III.

Table No.II- Effect of trial drugs on Haemoglobin level

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean B.T.</th>
<th>Mean A.T.</th>
<th>D</th>
<th>Change in %</th>
<th>S.D.</th>
<th>S.E.</th>
<th>T</th>
<th>P</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>9.8</td>
<td>11.03</td>
<td>1.23</td>
<td>13.59</td>
<td>1.2979</td>
<td>0.4104</td>
<td>2.9968</td>
<td>0.0150</td>
<td>S</td>
</tr>
<tr>
<td>B</td>
<td>9.92</td>
<td>11.28</td>
<td>1.36</td>
<td>14.20</td>
<td>1.1097</td>
<td>0.3509</td>
<td>3.8753</td>
<td>0.0037</td>
<td>H.S.</td>
</tr>
<tr>
<td>C</td>
<td>9.18</td>
<td>10.94</td>
<td>1.76</td>
<td>18.93</td>
<td>1.1635</td>
<td>0.3679</td>
<td>4.7834</td>
<td>0.0009</td>
<td>H.S.</td>
</tr>
</tbody>
</table>


Table no. III- Analysis of variance (ANOVA) Test for intergroup comparison

<table>
<thead>
<tr>
<th>Hb %</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
<th>P Value</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.23</td>
<td>1.36</td>
<td>1.76</td>
<td>0.5911</td>
<td>N.S.</td>
<td></td>
</tr>
</tbody>
</table>

Discussion

Significant result was observed in group A, while highly significant results were observed in group B and group C. Although *Pippali, lauha bhasma* and *pippali with lauha bhasma* all were effective in increasing Hb % as expected owing to high iron content in both *pippali* and *lauha bhasma* along with the bio availability enhancing property of *pippali*, quantitatively the most effective result (change in % 18.93) was seen in group C (*pippali with lauha bhasma*). Change in percentage in group A and group B was 13.59% and 14.20% respectively. No significant intergroup variation was observed among all the three groups. The results were in compliance with expected hypothetical outcome of this trial.

*Pippali* increases Hb% owing to its *deepana*, *srotoshodhana* and *rasayana* properties. *Lauha bhasma* contains iron (*dravya samanya*) and it effectuated increase in iron level on the basis of *samanya siddhanta*. Hb contains most of the body iron (65%), therefore increase in iron leads to increase in Hb%.
**Pippali** is bio availability enhancer hence when administered along with **lauha bhasma** it increases the iron absorption, transportation and utilization ultimately increases in Hb%.

**Probable Mode of the Action** - The mode of action of medicinal substances in *Ayurveda* is explained by *Charaka.* The medicinal substances can act on the basis of their *guna* (rasa, virya, vipaka, guna) and their *prabhava*. Accordingly it may be postulated that the trial drugs did elicit their action and effect as given in Table IV

<table>
<thead>
<tr>
<th>Drug</th>
<th>Parameter</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pippali</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rasa</td>
<td>Katu</td>
<td>Agni deepana and pachana</td>
</tr>
<tr>
<td>Guna</td>
<td>Tikshna</td>
<td>Srotoshodhana</td>
</tr>
<tr>
<td>Virya</td>
<td>Ushna</td>
<td>Deepana</td>
</tr>
<tr>
<td>Vipaka</td>
<td>Madhura</td>
<td>Dhatu poshana</td>
</tr>
<tr>
<td>Prabhava</td>
<td>Yogavahi</td>
<td>Iron</td>
</tr>
<tr>
<td><strong>Lauha bhasma</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prabhava and dravya samanya</td>
<td>Rakta vridhi</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rakta dhatu and iron</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rakta dhatu vridhi</td>
<td></td>
</tr>
</tbody>
</table>

Based on above table the sequence of drug action of trial drugs can be described as follows-

**Yat kurvanti (Karma)**- Agni deepana, Srotoshodhana, Dhatuposhana (Rasayana), increase bio availability of iron, Rakta vridhi (increase in rakta dhatu, Hb %)

**Yena kurvanti (Virya)**-

**Pippali**- Rasa- Katu,
Guna- Tikshna,
Virya- Ushna,
Vipaka- Madhura,
Prabhava- Yogavahi.

**Lauha bhasma**- Prabhava-rakta vridhi and dravya samanya- iron content

**Yatra kurvanti (Adhikaran)**- Jatharagni, Rasadhutwagni, Rakta-dhatwagni, Rasavaha srotas and Raktavaha srotasa.

**Yada kurvanti (Kala)** - The trial drugs exert their action in iron deficiency states.

**Yatha kurvanti-(Upaya)** - Pippali fruit powder when used in the dose of 2 gm/day, in divided doses with water and Lauha bhasma when used in the dose of 250 mg/day, in divided doses with water.

**Yatha kurvanti-(Upaya)** - Pippali fruit powder when used in the dose of 2 gm/day, in divided doses with water and Lauha bhasma when used in the dose of 250 mg/day, in divided doses with water.

**Yatha kurvanti-(Upaya)** - Pippali fruit powder when used in the dose of 2 gm/day, in divided doses with water and Lauha bhasma when used in the dose of 250 mg/day, in divided doses with water.

**References**

1. K. Sembulingam and Prema Sembulingam; Essentials of medical physiology; Jaypee brothers medical publishers; 6th edition; 2013; chapter 11; page no. 82.
Clinical Study

Clinical Evaluation of Pippalyadi Gandusha and Phalatrikadi Kwatha In The Management of Tundikeri W.S.R. To Tonsillitis

*Dr. Anubha Jain, **Prof. Shamsa Fiaz

Abstract

Tonsillitis though not is life threatening but troublesome and irritating disease reducing the quality of life of an individual in day to day activity. It is an infectious condition but if left untreated, may leads up to severe local and systemic complications like otitis media, sinus infections, peritonsillar abscess, Rheumatic fever, glomerulonephritis, etc. That's why it is important to pay attention towards this difficult disease.

In present study 44 patients of Tundikeri (tonsillitis) were studied into two groups. In group-I, patients were advised Pippalyadi Gandusha and in group-II, patients were advised Pippalyadi Gandusha and Phalatrikadi Kwatha orally. Better relief was observed in group II which received combined treatment followed by group I which received only Gandusha therapy, except in case of Paka (where group-I showed better result than group-II).

Key Words : Tundikeri, Tonsillitis, Pippalyadi, Gandusha, Phalatrikadi.