A COMPARATIVE STUDY OF PADMADI LAUHA AND IRON FOLIC ACID IN MANAGEMENT OF GARBHINI PANDU

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ABSTRACT

Aim: To evaluate the efficacy of padmakadi lauha in cases of Garbhini pandu. Introduction: Pandu means pallor of body which can be correlated with 'Anaemia' of modern science. Bala varna hani of Garbhini in 6th month of pregnancy can be considered as reference for Garbhini pandu. Anaemia is the commonest hematological disorder that may occur in pregnancy. Setting and Design: For the present clinical study 30 patients were selected. The patients having daurbalya, Shrama (Exhaustion), Bhrama (Giddiness), Jwara (Pyrexia), Jwara (Pyrexia), Nidralu (Over Sleep), Pidikodwesta (Cramps in Shanks), Hatprabha (Loss of Skin Lusture), Shoonakshi Koot (Swelling around Eye orbit) ,and Haemoglobin below 10gm% and above 6gm% were selected for present clinical study. Materials and method: All patients were divided in two groups -1. Group – A: Patients of this group were given Iron (Ferrus Ascorbate) 100 mg and Folic acid 1.5mg orally once a day after meal during a period of 12 weeks. 2.Group – B: Patients of this group were given Padmadi Lauha 500 mg BD orally after meal with fresh water for a period of 12 weeks. Type of study: Phase 2 Rationale Randomized control trial. Statistical analysis used: p value, paired ‘t’ test, unpaired ‘t’ test, χ² etc. Results: The trial drugs shows a significant results in terms of cure & improvement in subjective and objective parameters and no any side effect has been observed. Conclusion: In cured patients response of treatment in group A is more than group B however group B has good response in improved patients so this study concluded that both groups has significant response on all the sympotms but inter group comparision have not statistically significant.

KEYWORDS: Pandu, Garbhini Pandu, padmakadi lauha, Anemia in pregnancy.

INTRODUCTION

Clinical entity of Pandu (Anaemia) is as old as history of medicine itself. With the recent advances in the field of medicine our knowledge about disease has increased significantly. In Ayurveda term Pandu has originated from specific colour and has been described like Shukla, Peeta, Pandur, Ketaki Dhool Sannibha. The normal colour of our body is pinkish red, when this colour is converted into Pandur or Shukla Peeta or yellowish white then this colour denotes presence of Pandu Roga and due to this Charak has described that there is Kshaya or loss of Verna or general complexion.[1]

Though there is no direct reference of Garbhini pandu in Ayurvedic classics but term Varna hani in Garbhini resembles closely Panduroga, which is considered as Pitta Dosha pradhan. Acharya Charaka in Sharira sthana has explained about Bala varna hani of Garbhini in 6th month of pregnancy. It can be considered as reference for Garbhini pandu.[2] In pregnancy, nutrition is used for nourishment of garbhini, her foetus, placenta and breast. So nutritional requirements are high during pregnancy.[3] Which if not fulfilled, lead to deficiency disorders like anaemia.

Anaemia is the commonest hematological disorder that may occur in pregnancy.[4] The World Health Organization estimates that 58% of pregnant women in developing countries are anaemic. During pregnancy plasma volume expands maximum around 32 weeks, resulting in Haemoglobin dilution. Haemoglobin level below 10.0 gms/dl at any time during pregnancy is considered as anaemia. The two most common causes of anaemia during pregnancy are iron deficiency and acute blood loss. Iron deficiency anaemia is the most common nutritional disorder in the world that affects particularly women of reproductive age. Illiteracy is also a problem.
in developing countries like India due to which great majority of people do not pay attention to their dietary intakes. Even pregnant ladies don't get proper nourishment due to which mother child’s mortality is at higher level in developing countries.

According to charkha pandu is a rasa pradoshaja vikara. Clinical features of garbhini Pandu are same as pandu Roga. These are Daurbalya (Debility), Hatanal (Anorexia), Shrama (Exhaustion), Bhrama (Giddiness), Jwara (Pyrexia), Swas (Dyspnoea), Gatra Shool (Pain in body), Nidralu (Over sleep), Shishir Dweshi (Aversion to cold), Hatprabha (Loss of Skin Lusture), Shool (Pain in Lower Body), Nidralu (Over sleep), Shishir Dweshi (Aversion to cold), Hatprabha (Loss of Skin Lusture), Shool (Pain in Lower Body), Nidralu (Over sleep), Shishir Dweshi (Aversion to cold), Hatprabha (Loss of Skin Lusture). Hence Shama treatment can be adopted in Garbhini pandu. Thus we selected Padmakadi lauha for this study.

MATERIAL AND METHOD

Source of Data: For the present clinical study patients were selected from OPD and IPD of State Ayurvedic Medical College and Hospital, Aligarh as well as referred cases from other institutions.

Criteria for the selection of patients

Inclusion Criteria
1. Age group: 20 - 40 years
2. Socioeconomic status: All
3. Primi and multigravida.
4. 2 and 3 trimester of pregnancy were selected irrespective of religion.

Subjective criteria
1. Daurbalya (Debility)
2. Shrama (Exhaustion)
3. Bhrama (Giddiness)
4. Jwara (Pyrexia)
5. Swas (Dyspnoea)
6. Nidralu (Over Sleep)
7. Pidikodwesta (Cramps in Shanks)
8. Katiurupad Rukasdhani (Pain in lower Body)
9. Hatprabha (Loss of Skin Lusture)
10. Shoonakshi Koot (Swelling around Eye socket)

Objective criteria
1. Blood picture with microcytic hypochromia and normocytic hypochromia.
2. Hb% below 6 gms%.
3. Cases of Anaemia other than iron deficiency anaemia like thalasemia, Sickle cell anaemia, Pernicious anaemia. Haemolytic anaemia and Aplastic anaemia.
4. Anaemia associated with bleeding piles and other bleeding disorders.
5. Multiple pregnancy
6. High risk cases of Preeclampsia or eclampsia, Gestational diabetes,
7. Other systemic disease like Renal disease, Diabetes Jaundice etc.

Type of Study: Phase-2, rational, randomized (sequential) controlled trial.

Sample size: Total 30 patients were selected for this study.

Study plan
1. Informed consent was taken from all the patients before including them in the trial.
2. A special case Proforma was designed which consists of all the important data related to patients of Garbhini Pandu, treatment adopted & other information.
3. Standard scorings were given for the subjective as well as objective parameters for the assessment before & after treatment.

Period of Study: Total duration of clinical trial is of 3 months or 12 weeks.

Follow up Period: 1 month after treatment with two follow up at 15 days.

Grouping and posology: All the patients of Garbhini Pandu selected for clinical trial were randomly divided into two groups having 15 patients in each group.
1. Group – A: Patients of this group of Garbhini Pandu were given Iron (Ferrus Ascorbate) 100 mg and Folic acid 1.5mg orally once a day after meal with fresh water for a period of 12 weeks.
2. Group – B: Patients of this group of Garbhini Pandu were given Padmadi Lauha 500 mg BD orally after meal with fresh water for a period of 12 weeks.
Ingredients & Quantity of each ingredient in Padmadi Lauha are:

a. Padma (Nelumbo nucifera) - 80 mg
b. Yastimadhu (glycyrrhiza glabra) - 80 mg
c. Amla (Embrelcica officinalis) - 80 mg
d. Vibhitaki (Terminalia bellirica) - 80 mg
e. Haritaki (Terminalia chebula) - 80 mg
f. Lauha Bhasma (Iron ash) - 100 mg

DIET: During trial period patients were kept on their usual diet but they were advised to avoid tea, coffee, smoking (if addicted) chillies, spices and fried articles in their diet as far as possible.

Criteria of assessment
The result of treatment was assessed on the basis of improvement in the subjective and objective criteria with the help of suitable scoring method. Both subjective & objective assessments were done in all the patients before & after treatment. Hb% was done in all patient before treatment & after follow up period.

Criteria for the assessment of overall effect of the therapies
Assessment of results of the clinical trial in the present series of patients had been grouped into 3 categories:-

1. Relieved – (100% - 75%) The patients showing complete recovery of clinical symptoms and signs as well as pathological ground.
2. Moderate Improvement - (75% - 40%) Relief in almost all symptoms and signs of the patient with marked but below normal improvement in Haematological values.
3. Mild improvement - (< 40%) Relief in symptoms and signs of the patient with marked but below normal improvement in Haematological values.

Statistical analysis
For statistical analysis Student’s paired ‘t’ test was used for assessing the difference between groups. The obtained results were interpreted as non-significant p > .05, significant p < .01 and highly significant p < .001. The chi-square test was used for subjective parameters. Z value for inter group comparision.

RESULT
In the present clinical trial total 30 patients were registered. The present data are analyzed on the basis of total 30 patients, out of which 15 patients of group A and 15 patients of group B. The Comparative study of the Symptomatology as well as the pathological investigation were performed before and after treatment provided following results:-

Aetiological observation
In the present clinical study, it was found that the age group of 21-30 years comprises the maximum number of patients 20 (66.67%). Maximum number of patients (70%) were Hindu according to religion. Maximum number of patients 24 (80%) was house wife. Maximum number of the patients (80%) belonged to low income group. Maximum number of patients (66.67%) were non vegetarian. Maximum number of patients (40%) were illiterate and 50% having poor hygiene. Tobacco Chew was most common Addiction 20% patients have it, 66.67% patients found in group of no addiction.

Clinical observations
All the registered patients were clinically analyzed according textual description. Each and every symptom was observed in each patient. A thorough physical and systemic examination has been done. It was observed that before use of trial regime most of the patients showed Daurbalya (Debility) 96.7%, Shrama (Exhaustion) 83.33%, Bhrama (Giddiness) 80.00%, Jwara (Pyrexia) 56.67%, Swas (Dyspnoea) 50.00%, Nidralu (Over Sleep) 56.67%, Pidikodwesta (Cramps in Shanks) 73.33%, Katuuprad Ruksadnani (Pain in lower Body) 50.00%, Hatprabha (Loss of Skin Lustre) 100%, Shoonakshi Koot (Swelling around Eye Socket) 43.3%.

Therapeutical observations
The drug regimen has shown their effect in almost all the symptomatology.

Daurbalya (Debility) was present in 14 (93.3%) patients in Group-'A' and 15 (100%) in Group-'B' cases before treatment. After treatment 10 patients (71.3%) in Group-'A' and 9 patients (60%) in Group-'B' were relieved. 4 patients in Group-'A' and 5 patients in Group-'B' were improved. Shrama (Exhaustion) was present in 12 (80%) cases in Group-'A' and 13 (86.67%) cases in Group-'B' before treatment. After treatment 7 patients (58.33%) in Group-'A' and 7 patients (53.84%) in Group-'B' were relieved. 5 patients in Group-'A' and 6 patients in Group-'B' were improved. Bhrama (Giddiness) was present in 12 (80%) cases in Group-'A' and 12 (80%) cases in Group-'B' before the treatment. After treatment 10 (83.3%) patients in Group-'A' and 9 (75.0%) patients in Group-'B' were relieved. 2 patients in Group-'A' and 3 patients in Group-'B' were improved. Jwara (Pyrexia) was present in 9 (60%) cases in Group-'A' and 8 (53.33%) cases in Group-'B' before the treatment. After treatment 8 (88.9%) patients in Group-'A' and 6 (75%) patients in Group-'B' were relieved. Swas (Dyspnoea) was present in 7 (46.67%) cases in Group-'A' 8 (53.33%) cases in Group-'B' before the treatment. After treatment 6 (85.71%) patients in Group-'A' and 6 (75%) patients in Group-'B' were relieved. 1 patients in Group-'A' and 2 patients in Group-'B' was improved. Nidralu (Over Sleep) was present in 8 (53.33%) cases in Group-'A' 9 (60%) cases in Group-'B' before the treatment. After treatment 7 (87.5%) patients in Group-'A' and 7 (77.8%) patients in Group-'B' were relieved. 1 patients in Group-'A' and 2 patients in Group-'B' was improved. Pidikodwesta (Cramps in Shanks), was present in 10 (66.67%) cases in Group-'A' 12 (80%) cases in Group-'B' before the treatment.
treatment. After treatment 7 (70%) patients in Group-'A' and 8 (66.7 %) patients in Group-'B' were relieved. 3 patients in Group-'A' and 2 patients in Group-'B' was improved. **Katiurupad Ruksadnani (Pain in lower Body)** was present in 8 (53.33%) cases in Group-'A' 9 (60%) cases in Group-'B' before the treatment. After treatment 6 (85.71%) patients in Group-'A' and 6(75 %) patients in Group-'B' were relieved. 2 patients in Group-'A’ and 2 patients in Group-'B' was improved. **Hatprabha ( Loss of Skin Lusture)** was present in 15 (53.33%) cases in Group-'A’ 15 (60%) cases in Group-'B' before the treatment. After treatment 10 (66.7%) patients in Group-'A’ and 9 (60 %) patients in Group-'B’ were relieved. 4 patients in Group-'A’ and 3 patients in Group-'B’ was improved. **Shoonakshi Koot (Swelling around Eye Socket)** was present in 7 (53.33%) cases in Group-'A’ 6 (60%) cases in Group-'B’ before the treatment. After treatment 6 (85.71%) patients in Group-'A’ and 5 (83.33 %) patients in Group-'B’ were relieved. 1 patient in Group-'A’ and 1 patient in Group-'B’ was improved.

**Table 1: Significance of treatment on different signs and symptoms.**

<table>
<thead>
<tr>
<th>S. No</th>
<th>Name of Symptoms</th>
<th>Statistical Assessment</th>
<th>Inter group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Group ‘A’</td>
<td>Group ‘B’</td>
</tr>
<tr>
<td>1.</td>
<td>Daurbalya (Debility)</td>
<td>71.43%</td>
<td>31.4</td>
</tr>
<tr>
<td>2.</td>
<td>Shrama (Exhaustion)</td>
<td>58.33%</td>
<td>17.42</td>
</tr>
<tr>
<td>3.</td>
<td>Bhrama (Giddiness)</td>
<td>83.3%</td>
<td>17.59</td>
</tr>
<tr>
<td>4.</td>
<td>Jwara (Pyrexia)</td>
<td>88.9%</td>
<td>13.2</td>
</tr>
<tr>
<td>5.</td>
<td>Swas (Dyspnoea)</td>
<td>85.71%</td>
<td>9.62</td>
</tr>
<tr>
<td>6.</td>
<td>Nidralu (Over Sleep)</td>
<td>87.5%</td>
<td>9.34</td>
</tr>
<tr>
<td>7.</td>
<td>Fidikodwesta (Cramps in Shanks)</td>
<td>70%</td>
<td>7.82</td>
</tr>
<tr>
<td>8.</td>
<td>Katiurupad Ruksadnani (Pain in lower Body)</td>
<td>85.71%</td>
<td>8.64</td>
</tr>
<tr>
<td>9.</td>
<td>Hatprabha ( Loss of Skin Lusture)</td>
<td>66.7%</td>
<td>20.64</td>
</tr>
<tr>
<td>10.</td>
<td>Shoonakshi Koot (Swelling around Eye Socket)</td>
<td>85.71%</td>
<td>7.62</td>
</tr>
</tbody>
</table>

**Table 2: The effect of treatment on laboratory investigations.**

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Group</th>
<th>Mn + SD</th>
<th>Change in Mn + SD</th>
<th>t</th>
<th>p</th>
<th>% Imp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb %</td>
<td>A</td>
<td>8.6+3.42</td>
<td>12.4+3.68</td>
<td>3.80 +1.86</td>
<td>7.96</td>
<td>&lt;.001 S</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>8.4+4.12</td>
<td>11.8+4.20</td>
<td>3.40 +2.01</td>
<td>6.59</td>
<td>&lt;.001S</td>
</tr>
<tr>
<td>RBC</td>
<td>A</td>
<td>2.68+0.56</td>
<td>3.59+0.68</td>
<td>0.91 +0.34</td>
<td>10.4</td>
<td>&lt;.001S</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>2.36+0.62</td>
<td>3.10+0.72</td>
<td>0.74 +0.40</td>
<td>7.22</td>
<td>&lt;.001S</td>
</tr>
<tr>
<td>PCV</td>
<td>A</td>
<td>26.8+4.56</td>
<td>34.6+5.82</td>
<td>7.8 +2.42</td>
<td>12.6</td>
<td>&lt;.001S</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>25.9+5.2</td>
<td>32.8+6.30</td>
<td>6.9 +2.86</td>
<td>9.41</td>
<td>&lt;.001S</td>
</tr>
<tr>
<td>MCHC</td>
<td>A</td>
<td>32.5+6.24</td>
<td>34.9+5.48</td>
<td>2.36 +0.78</td>
<td>11.8</td>
<td>&lt;.001S</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>32.3+5.96</td>
<td>34.5+6.48</td>
<td>2.14 +0.64</td>
<td>13.0</td>
<td>&lt;.001S</td>
</tr>
</tbody>
</table>

**Table 3: The overall effect of therapy in both groups A & B.**

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Group</th>
<th>Relieved No. of patients</th>
<th>% Age</th>
<th>Moderate Improvement No. of patients</th>
<th>% Age</th>
<th>Mild Improvement No. of patients</th>
<th>% Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>‘A’ (Iron-folic acid)</td>
<td>6</td>
<td>40%</td>
<td>6</td>
<td>40%</td>
<td>3</td>
<td>20%</td>
</tr>
<tr>
<td>2</td>
<td>‘B’ (Padmadi lauha)</td>
<td>5</td>
<td>33.3%</td>
<td>7</td>
<td>46.7%</td>
<td>3</td>
<td>20%</td>
</tr>
</tbody>
</table>

**Graph showing total effect of therapy**

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DISCUSSION

Though there is no direct reference of Garbhini pandu in Ayurvedic classics but term Varna hani in Garbhini resembles closely Panduroga, which is a Pitta pradhan tridoshaj vyadhi. In all types of pandu pitta is a root cause. In Ayurveda there are two line of treatment for all types of disease. Shodhana is the first and shamana is second line of treatment. But shodhana is contraindicated in Garbhini. The disorders of the pregnant woman should be treated with diet and drugs consisting of mridu veerya (mild potency), Madhur(sweet rasa), sheeta (cold) vipaka and properties which are non contrary to fetus. This implies that proper nutrition along with pitta pacifying measures are the main stream of management. Hence Shamana treatment can be adopted in Garbhini pandu. Thus we selected Padmakadi lauha for this study.\(^{[10]}\)

The contents of trial drug Padmadi Lauha consisting of all the above mentioned properties. The trial drug contains padam, Yastimadhu, Triphala, and lauhabhasma. Padam has madhur rasa, madhur vipaka and sheeta veerya due to which it has pittashamak and Garbhashthapak property. Because of the Amino acids present in padam it helps to prevent.

Oligohydrominios. Yastimadhu also a madhur rasa, madhur vipaka and sheeta veerya aushdhi. It also pacified the pitta dosha and very effective in dyspepsia. Sothat it is very useful in gastric irritation produced by iron therapy.

Triphala contains Amalaki, Haritaki and Vibhitak. Amalki is Sheet Virya, Madhur Vipak, Tridosh Hara, and Rasayana in quality. Amalaki is a rich source of vitamin C which helps in absorption of Iron. Triphla as a whole has very good effect because this contains mild laxative property. Constipation is a very common symptom found in pregnancy and it increases with iron therapy so many of the patient stop the treatment in mid term. This drug also helpful in these cases as constipation was not found in any case during the treatment and after treatment. Lauha Bhasma was here to supply elemental Iron for good haemopoietic effect, although several methods are there to prepare the Lauha Bhasma but the most effective is that prepared with Triphala Kwath.

The effect of the drug leads to improvement of metabolism, RBCs production, mineral supplement and consumption in body and relief from the disease. So that this preparation fulfilled all the requirements. This drug was very effective on all the symptoms of pandu (Anaemia). It has good and rapid response even if used alone. It was also very effective to certain extent on other predisposing factors of the Garbhini Pandu. It was easy to administer. It should be having no toxic effects. The present drug selected for the study on Garbhini Pandu Roga did not show any side effect in the (present cases) course of study. The recurrence of the symptoms after withdrawal of the drug during the follow up period was least.

CONCLUSION

On the basis of present clinical trial following conclusion have been drawn-

1. Garbhini Pandu is considered as anemia in pregnancy in the present study. Garbhini Pandu is the disease entity which comes as part and parcel with pregnancy.
2. Formulation of drug Padmadi Lauha was on the basis of Rasendra Sara Sangrah. This drug shows a wide range of acceptability among all the age group cases of Garbhini Pandu.
3. Most common symptom, constipation in the patients of Anaemia on the Iron therapy, was not at all found in any case in the present study, so it can freely be advocated in Anaemia of pregnancy and Anaemia due to anorectal problems, where constipation may create problem and which may be the cause of Anaemia itself.
4. The present drug selected for the study on Garbhini Pandu Roga did not show any side effect in the (present cases) course of study. The recurrence of the symptoms after withdrawal of the drug during the follow through period was least.
5. On the basis of cost wise expenditure this present drug is cheaper in comparison with other effective haematinics. Thus the regimen may prove a valuable contribution from Ayurveda towards the ailing humanity.
6. It is further suggested that a clinical drug trial of this Padmadi Lauha must be under taken in a larger number of cases so that the results of the present study could be verified on further grounds with finer details.

Conflicts of interest: Nil.

Source of support: Nil.

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