Research Article

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A CLINICAL STUDY ON THE EFFECT OF DHATRI LAUHA IN GARBHINIPANDU (IRON DEFICIENCY ANAEMIA)

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ABSTRACT

Women are treasured by the richness of continuing the human race. Pregnancy is a state in which all the physiological functions are hyper stimulated in order to meet the demands of the growing fetus. Anaemia during pregnancy is a very common condition which involves the fall in the hemoglobin concentration. The prevalence of Anaemia in low-income pregnant women in the 1st, 2nd and 3rd trimesters is 9 %, 14 % and 37 %, respectively. Iron deficiency Anaemia results in decreased work productivity, increased child mortality, increased maternal mortality, slowed child development, and mild-to-moderate Anaemia may increase susceptibility to infectious disease. The features of Iron Deficiency Anaemia (IDA) shares lot similarities with lakshana of Panduroga. In this open labeled clinical trial, 50 pregnant women fulfilling the diagnostic and inclusion criteria of Panduroga / Iron Deficiency Anaemia (IDA) were administered with Dhatri Lauha with a dose of 500 mg thrice a day orally for 4 weeks. In the present study Dhatri Lauha showed a highly significant improvement in terms of subjective parameters like Panduta, Hriddrava, Daurbalya, Shrama and Bhrama as well as in objective parameters like Hb %, RBC, PCV, MCV, MCH, MCHC (< 0.001). This study has revealed that Dhatri Lauha provided statistically significant improvement in the cardinal features of Garbhinipandu as well as it has showed good effect on jatharagni and nourishment of pregnant woman and foetus without any side effects, due to the properties of the ingredients of trial drug such as deepana, pachana, balya, rasayana and rudhirakrit.

Keywords: Garbhini pandu, Iron Deficiency Anaemia (IDA), Dhatri Lauha

INTRODUCTION

Anaemia is defined as reduction in circulating haemoglobin below the critical level. The normal haemoglobin (Hb) concentration in the body is between 12-14 grams percent. WHO has accepted up to 11 g percent as the normal hemoglobin level in pregnancy. In India and most of the other developing countries the lower limit is often accepted as 10 g %[1]. Anaemia is often classified according to Haematocrit (PCV) % as mild degree (9-11 g %), moderate (7-9 g %), severe (4-7 g %) and very severe (< 4 g %).[2] Anemia in pregnancy is present in very high percentage of pregnant women in India. According to WHO in India incidence of Anaemia during pregnancy has been noted as high as 40-80 %.[3] Among pregnant women, Iron Deficiency Anaemia (IDA) during the first two trimester's results in increased incidence of preterm labor and low-weight births. The prevalence of Anemia in low-income pregnant women in the 1st, 2nd and 3rd trimesters is 9 %, 14 % and 37 % respectively. Iron deficiency Anaemia results in decreased work productivity, increased child mortality, increased maternal mortality, slowed child development, and mild-to-moderate Anaemia may increase susceptibility to infectious disease[4]. Sociodemographic factors, Obstetrical factors, Behavioral factors, Medical conditions are the common risk factors of anemia in pregnancy. The common clinical presentation of anemia in pregnancy is pallor of skin, pale nails, pale tongue, glossitis, stomatis and other symptoms include lassitude, fatigue, anorexia, indigestion, palpitation, dyspnoea, giddiness, oedema and pica[5]. These features share lot similarities with lakshana of Panduroga. Acharya Harita has described eight Garbhopadravas[6] and included Vivarnatva, which appears to be pallor that accompanies anemia. Panduroga is a varnopalakshita vyadhi, where pandutwa or pallor of the skin is the predominant feature and the other lakshana are alparakta, alpameda, nissara and sithilendriya. In addition there will be Dourbalya, Karshya, Karnakshweda, Gatrapeeda, akshikootashotha, Sheernalomata, Hridrava, Shwasa, Bhrama and Annadwesha[7]. Panduroga Chikitsa includes both shodhana and shamana[8]. Garbhini should be treated just like a pot filled with oil, slightest oscillation of such pot causes spilling of oil. Similarly slightest excitement to the pregnant woman can initiate abortion, etc. In shamana Chikitsa, various single and compound preparations are told which include herbal, mineral and herbo-mineral preparations. The analysis of the formulations mentioned in the context of Pandu indicates that they contain herbal ingredients like Shunthi, Maricha etc which can improve the Agni and metabolism and thus relieves Pandu. Dhatri Lauha[9], mentioned in Chakradutta, is a herbo-mineral preparation with ingredients like Vyosha, Dhatriand Loha Bhasma, which are Deepana, Rasayana and iron supplementation respectively that results in correction of jatharagni, in turn leads to dhatuposhana as well as Rasayana and Shonitasthapana. Dhatri Lauha is easily dispensable, cost effective and with easily available ingredients. Hence, this study was planned to assess the therapeutic effect of Dhatri Lauha in Garbhinipandu/IDA.

MATERIALS AND METHODS
Study Design
Open label, Single blind clinical study with Pre and Post test design.

Drug Source
The required herbal formulation Dhatri Lauha was prepared specially for the study in S.D.M. Ayurveda Pharmacy- Udupi, Karnataka, India.

Method of collection of data
Patient Source
Pregnant women suffering from Panduroga (IDA) were selected from OPD and IPD of S.D.M. Ayurveda Hospital, Udupi, Karnataka, India.

Sample Size
Minimum of 50 pregnant women fulfilling the diagnostic and inclusion criteria of Panduroga (IDA), irrespective of their caste, economical and educational status, were selected for the study. The study was commenced after obtaining approval (letter No. SDMCAU/ACA15/EC–01/10-11 Dt. 04th April 2010) of Institutional Ethical Clearance Committee.

Preparation of Dhatri Lauha
Properly cleaned raw drugs dhatri, shunti, maricha, pippali and nisha (Table 1) were made into powder separately and sieved through clean cloth and mixed well. Lohabhasma was added and mixed together thoroughly to get homogeneous mixture. This mixture was transferred into the punching machine and prepared vati of 500 mg size.

Selection criteria
Diagnostics Criteria
Signs and symptoms of Panduroga/IDA
Hemoglobin less than10 g %
RBC – less than 4 million /mm³
PCV – less than 30 %
MCV – less than 75 µ m³
MCH – Less than 25 pg
MCHC – less than 30%
Blood picture with Microcytic Hypochromia and Normocytic Hypochromia[10]

Inclusion Criteria
Patients fulfilling diagnostic criteria
Patients aged between 18 – 40 years age
Both primi and multi gravida in their 2nd trimester
Hemoglobin below 10 g% and above 7 g%
Blood picture with Microcytic Hypochromia and Normocytic Hypochromia

Exclusion Criteria
Patients with Anemia other than Iron Deficiency Anaemia
Patients with Hemoglobin below 7 g percent
Patients suffering from Iron deficiency Anaemia due to other Systemic disorders/ Infections like Hepatic cirrhosis, Rheumatoid arthritis, Uremia and Malignant disorders.

Intervention and Follow-up
Dhatri Lauha (DL) 500 mg thrice a day for 4 weeks and followed till delivery.

Assessment Criteria
All the data was collected and documented as a detailed case proforma. Assessment of the disease was done adapting standard methods of scoring. Subjective and objective parameters were analyzed statistically.

Subjective Parameters
Arohanayasa (Exertional Dyspnoea)
Dourbalya (Generalized weakness)
Hriddrava (Palpitation)
Pandutva of Netra, Nakha (Pallor)
Shotha (Oedema)
Agnimandya (Loss of Appetite)
Angamarda (fatigue)
Shiroruja (headache)
Rukshangata (Dryness)
Alasya (Lassitude)

Objective Parameters
Hemoglobin (Hb)
Red blood cell count (RBC Count)
Hematocrit (Hct/PCV)
Mean corpuscular volume (MCV)
Mean corpuscular hemoglobin (MCH)
Mean corpuscular hemoglobin concentration (MCHC)

OBSERVATIONS
Out of 50 patients registered for the present study, maximum number of patients, i.e., 52 % belonged to age group of 26-30 years, 72 % were of Hindu community, 86 % were of Middle Income group, 64 % patients were having high school education, 76 % patients belonged to rural area, 52 % were housewives, 98 % were of mixed diet, 72 % patients were having anoopa mamsa sevana, 38 % patients had Vata-Pitta Prakriti and 68 % had Mandagni (Table 2, 3 and 4). Out of 50 pregnant women screened for present study, all patients (100 %) were having the complaints of Daurbalya (weakness) and Shrama (fatigue), 96 % patients had Bhrama (dizziness), 86 % had Hriddrava (palpitations), 84 % had Panduta (pallor), 78 % had Arohanayasa (Exertional Dyspnoea), 56 % had Sirasshola (headache) and 54% had the complaint of Aruchi (tastelessness). (Table 5)

RESULTS
Patients suffering from Garbhinipandu / IDA were treated with Dhatri Lauha in a dose of 500 mg thrice a day for 28 days in this single blind, pre-test and post-test clinical trial. The effect of the treatment following medication was assessed with regards to subjective and objective criteria before and after the trial period. Statistical analysis was performed with computer statistical package SIGMASTAT (Version 3.5). Data was presented as mean ± SEM. The results were analyzed for statistical significance using paired 't' test. A P-value < 0.05 was considered significant.

Effect on Subjective and Objective Criteria
In the present study, Dhatri Lauha provided relief in majority of the Subjective Parameters of Garbhinipandu. The result observed in Panduta (Pallor), Hriddrava (Palpitation), Daurbalya (Weakness), Shrama (Fatigue) and Bhrama (Dizziness) were highly significant statistically (< 0.001). Aruchi (Tastelessness), Arohanayasa (Dyspnoea), Sirasshola (Headache) and Irritability results after treatment were found statistically significant ($P < 0.05$) (Table 6). The Objective Parameters i.e. Hb %, RBC, PCV, MCV, MCH, MCHC results after treatment were found highly significant statistically (< 0.001) whereas the WBC results after treatment shown the significance ($P < 0.05$) (Table 7).

DISCUSSION
Gabhinipandu (IDA) can be taken as a Rasapradoshajavikara, which is common in Garbhavastha (pregnancy). Consumption of food substances having Amla, Lavana, Katurasa excessively, practicing Abhojana, Pramitabhojana etc., during pregnancy and Dauhridavastha, were found as etiological factors for Garbhinipandu. In the present study, majority of pregnant women (52 %) were in between the age group of 26-30 years which indicates the vivardhamana dhatuavastha of the pregnant woman and increased demand of nutrition from the developing foetus results in Anaemia. Patients were having the nidana like anoopamamsa sevana (72 %) and asatmya (56 %), viruddhabhojana (56 %) and leading to Mandagni (68 %) creates Ama production and improper Rasadhatu formation which is the main cause for manifestation of Pandu. In the present study, a statistically significant improvement was observed in both subjective and objective parameters. Dhatri Lauha contains Shunti, maricha and Pippali which are Deepana Pachana, Kaphavatahara, and Amadoshaharaas well as Srotoshodhaka properties that cause agnideepti and in turn leads to proper metabolism as well as formation of proper Dhatus. Amalaki, which is a rich source of Vitamin C, is known enhancer of iron absorption. It also contains Nisha which is Pitta Virechaka and varnya, thus corrects Pitta and Rakta. Lauha Bhasma, the iron supplement, has deepana, balya, rasayana and raktavardhaka properties which lead to proper metabolism and dhatuposhana. Thus, the collective effect of all the ingredients leads to improvement of metabolism, iron absorption, improved blood formation and relief from the disease[11].

Table 1: Ingredients of Dhatri Lauha

S. No.	Drug	Scientific Name and Family	Part used	Quantity	Action
1.	Dhatri	*Phyllanthus emblica* Linn. Euphorbiaceae	Fruit pulp	3 parts	Chakshushya, Rasayana, Tridoshajit, Vrishya, Rochana, Deepana, Balya, Anulomana, Garbhasthapana
2.	Shunti	*Zingeber officinale* Roxb. Zingeberaceae	Rhizome	1 part	Anulomana, Deepana, Hridya, Pacana, Vatakaphapaha, Amadoshahara
3.	Maricha	*Piper nigrum* Linn. Piperaceae	Seed	1 part	Sleshmahara, Deepana,Medohara, Pittakara,Rucya,Kaphavatajit, Vatahara, Chedana, Jantunasana, Srotosodhana
4.	Pippali	*Piper longum* Linn. Piperaceae	Seed	1 part	Deepana, Hridya, Kaphahara, Ruchya, Tridoshahara, Vrishya, Rasayana,
5.	Nisha	*Curcuma longa* Linn. Zingeberaceae	Rhizome	3 parts	Krimighna, Kushtaghna, Varnya, Vishaghna, Kaphapittanut,
6.	Loha Bhasma	-	-	3 parts	Balya,Vrshya, Ayushya,Vayasya, Rudhirakrt, Yogavahi, Rasayana

Table 2: Demographic observations

S. No.	Observations	Maximum	No. of Patients	Percentage
1.	Age	Vivardhamana	26	52
2.	Religion	Hindu	36	72
3.	Education	High school	32	64
4.	Occupation	House Wife	26	52
5.	Economic Status	Middle income group	43	86
6.	Habitat	Rural Area	38	76
7.	Diet	Mixed	49	98
8.	Gravida	Primi	25	50
9.	Bowel Habits	Regular	47	94

Table 3: Observations of Ayurvedic Parameters

S. No.	Observations	Maximum	No. of Patients	Percentage
1.	Prakriti	Vatapitta	19	38
2.	Satmya	Madhyama	32	64
3.	Sara	Madhyama	50	100
4.	Satwa	Madhyama	50	100
5.	Samhanana	Madhyama	50	100
6.	Pramana	Madhyama	50	100
7.	Ahara Shakti	Madhyama	34	68
8.	Vyayama Shakti	Madhyama	34	68
9.	Koshta	Madhya	43	86
10.	Agni	Mandagni	34	68

Table 4: Observations of Nidana

S. No.	Nidana sevana	No. of Patients	Percentage
1.	Matsya Sevana	36	72
2.	Amla Sevana	31	62
3.	Asatmya Ahara	17	34
4.	Viruddhabhojana	28	56
5.	AdhikaPayah Sevana	34	68

Table 5: Observations of Clinical Features

S. No.	Clinical Features	No. of Patients	Percentage
1.	Artavaadarsana (Amenorrhoea)	50	100
2.	Daurbalya (Weakness)	50	100
3.	Shrama (Fatigue)	50	100
4.	Bhrama (Dizziness)	48	96
5.	Sirasshola (Headache)	28	56
6.	Hriddrava (Palpitation)	43	86
7.	Arohanayasa (Dyspnoea)	39	78
8.	Irritability	12	24
9.	Aruchi (Tastelessness)	27	54
10.	Panduta (Pallor)	42	84
11.	Pica	12	24
12.	Jihwasotha (Glossitis)	6	12
13.	Oshtasotha (Stomatitis)	9	18
14.	Karnakshwedha (Tinnitus)	7	14

Table 6: Effect of Dhatri Lauha on Subjective Parameters

Parameter	Mean ± SE		Paired 't' test			
	BT	AT	S.D	S.E	't'	P
Weakness	3.320 ± 0.135	2.120 ± 0.0840	1.010	0.143	8.400	< 0.001
Fatigue	2.240 ± 0.116	1.640 ± 0.0743	0.833	0.118	5.093	< 0.001
Dizziness	1.660 ± 0.0788	1.000 ± 0.107	1.022	0.145	4.565	< 0.001
Headache	0.700 ± 0.1000	0.680 ± 0.109	0.553	0.0782	0.256	0.799
Palpitation	1.280 ± 0.0991	0.860 ± 0.0700	0.883	0.125	3.364	< 0.001
Dyspnoea	0.980 ± 0.0925	0.700 ± 0.0958	1.031	0.146	1.920	0.061
Irritability	0.260 ± 0.0689	0.280 ± 0.0641	0.589	0.0833	0.240	0.811
Tastelessness	0.800 ± 0.118	0.540 ± 0.0819	0.944	0.133	1.949	0.057
Pallor	1.260 ± 0.114	0.780 ± 0.0823	0.677	0.0958	5.011	< 0.001
Pica	0.200 ± 0.0639	0.0600 ± 0.0444	0.351	0.0496	2.824	0.007
Glossitis	0.180 ± 0.0739	0.0600 ± 0.0444	0.480	0.0679	1.769	0.083
Stomatitis	0.200 ± 0.0639	0.0600 ± 0.0444	0.351	0.0496	2.824	0.007
Tinnitus	0.180 ± 0.0682	0.000 ± 0.000	0.482	0.0682	2.641	0.011

Table 7: Effect of Dhatri Lauha on Objective parameters

Parameter	Mean ± SE		Paired 't' test			
	BT	AT	S.D	S.E	't'	P
Hb	9.152 ± 0.0579	9.530 ± 0.108	0.585	0.0827	4.569	< 0.001
RBC	3.458 ± 0.0409	3.630 ± 0.0397	0.263	0.0373	4.617	< 0.001
PCV	28.278 ± 0.429	29.518 ± 0.429	2.323	0.329	3.774	< 0.001
MCV	78.940 ± 0.762	82.702 ± 0.900	4.797	0.678	5.545	< 0.001
MCH	26.932 ± 0.380	29.282 ± 0.355	2.849	0.403	5.832	< 0.001
MCHC	30.582 ± 0.406	32.430 ± 0.359	3.548	0.502	3.683	< 0.001
WBC	9528.40 ± 316.13	9882.00 ± 236.52	1544.53	218.43	1.619	0.112

Hb- Haemoglobin; RBC - Red Blood Cells; PCV- Packed Cell Volume; MCV - Mean Corpuscular Volume;
MCH - Mean Corpuscular Haemoglobin; MCHC - Mean Corpuscular Haemoglobin Concentration; WBC - White Blood Cells

CONCLUSION

Garbhinipandu can be correlated with Iron Deficiency Anaemia in pregnancy, which is commonly seen due to increased demand of nutrition from the developing foetus. In the present study Dhatri Lauha showed a highly significant improvement in terms of subjective parameters like Panduta (Pallor), Hriddrava (Palpitation), Daurbalya (Weakness), Shrama (Fatigue) and Bhrama (Dizziness) as well as in objective parameters like Hb %, RBC, PCV, MCV, MCH and MCHC (< 0.001). Amapachaka, Srotoshodhaka, Raktavardhaka and Rasyana properties of Dhatri Lauha causes the improvement of metabolism, iron absorption enhanced blood formation which in turn leads to relief of the symptomatology.

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