

Clinical Evaluation of an Ayurvedic Preparation for the Treatment of Iron Deficiency Anemia in Patients

Nazmul Huda Md^{1*}, Daya Shankar Mishra² and Singh JP²

¹Hamdard University, Bangladesh

²Department of Kayachikitsa, National Institute of Ayurveda, Jaipur, India

*Corresponding author: Nazmul Huda Md, Hamdard University, Bangladesh, Tel: +88-01712720025; E-mail: mdnazmulhudabd@yahoo.com

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Abstract

Iron deficiency anemia is the most widespread nutritional disorder in the world. Prevalence of anaemia in Indian subcontinent is high because of low dietary intake, poor availability of iron and chronic blood loss due to hook worm infestation and malaria. Numbers of preparations are available in Ayurveda for correction of Iron deficiency anemia. So this study was conducted to investigate the efficacy of two Ayurvedic formulations Dhatri louha and Novayas louha in anaemic patients. It was randomized, non-blinded, and placebo controlled pre-posttest design. Total thirty patients were divided into three groups. Each group contained 10 numbers of patients. Group 1 (control group) was given one starch capsule daily for 30 days and Group 2 and Group 3 were given two Ayurvedic formulations Dhatri louha and Novayas louha respectively in a dose of 250 mg twice a day for 30 days. Hematological parameters like hemoglobin concentration, packed cell volume, mean corpuscular volume, mean corpuscular hemoglobin and mean corpuscular hemoglobin concentration were determined before and after completion of treatment. After the 30 days of treatment it was found significant ($p < 0.05$) response in Group 2 and Group 3 when compared with Group 1. Therefore, it is claimed that Dhatri louha and Novayas louha have haemopoetic function although it was a preliminary work.

Keywords: Iron deficiency anemia (IDA); Dhatri louha; Novayaas louha

Introduction

Overall, Iron-deficiency anemia (IDA) is the most common type of anemia and is caused by insufficient dietary intake and absorption of iron, and/or iron loss [1]. It is a public health problem in both developing and industrialized countries and affects approximately 30 percent of the world's population [2]. Prevalence of IDA in developing countries as a whole is 36 percent and only 8 percent in developed countries [3]. Especially it is a very common phenomenon in developing countries including India, Bangladesh and Pakistan and particularly prevalent in women, infants and young children. A national survey of India has reported high prevalence rates of anemia 79.2 percent in children below 3 years of age and 56.2 percent in women aged 15-49 years and among them 50-95 percent of anemia is due to iron deficiency [4]. Insufficient level of iron in the blood makes fatigue, reduces physical activity, and effects on behavior, psychomotor development, and academic performance [5]. Severe iron deficiency can affect the cognitive performance in women of reproductive age. In pregnancy, it may increase the risk of pre-term delivery, low birth weight, and higher incidences of maternal mortality [6]. So it is a worldwide problem. According to Ayurvedic classics, sign and symptoms of Pandu Roga are very much similar to IDA. It develops due to depletion of Rasa Dhatu which in turn becomes ineffective the production of Rakta Dhatu [7]. Numerous iron containing modern medicines are available in all over the market and these contained one or more iron salts in the form of ferrous sulphate, ferrous fumarate, ferrous glycine sulfate, ferric hydroxide polymaltose complex, ferric ammonium citrate, iron dextran, iron choline citrate, iron sorbitol citrate, ferrous calcium citrate, ferrous gluconate,

colloidal iron hydroxide, ferrous succinate and ferric hydroxide. Oral administrations of these medicines are effective and inexpensive. But long term treatment may cause heartburn, nausea, upper gastric discomfort, constipation and diarrhea [8] and recent studies also showed long term oral administration of these preparations fails to correct the anaemia. Because excessive free iron accumulate in duodenal enterocytes which may generate free radicals via Fenton reaction and that leads to per-oxidative damage of the tissue [9]. Hence, alternative Ayurvedic medicine may play an important role to minimize the problem. There are various herbal and herbomineral preparations are mentioned in Ayurvedic classics for the management of iron deficiency anaemia. Some of them are - Amalapittantako Lauha, Chandanadi Lauha, Dhatri Lauha, Navayasa lauha, Pippaladhya Lauha, Pittantaka Lauha, Pradarantaka Lauha, Pradarari Lauha, Punarnavadi Mandura, Rohitaka Lauha, Saptamrata Lauha, Sarva-Juara-Hara Lauha, Triphala Lauha, Vrihat Yakrdari Lauha and Yakrdari Lauha. All the above preparations are claimed to have haemopoetic function. However, their scientific data is not available. Dhatri Lauha [10] and Navayasa lauha were selected for present study because they are available everywhere in country and cheap and claimed for the treatment of anaemia. So the aim of this study was carried out to investigate the efficacy of two Ayurvedic herbomineral preparations in response to IDA with a placebo drug.

Methods and Materials

The study was a randomized, non-blinded and placebo controlled design in human subjects with clinically established of iron deficiency anemic patient that confirmed by laboratory investigations. After following inclusion and exclusion criteria total 30 patients (female-18 and male-12) were selected from OPD and IPD of Kayachikitsa Department at National Institute of Ayurveda Hospital, Jaipur, India.

Patients who were 18-70 years age range either male or female and hemoglobin concentration is less than 12 gm/dl in men or less than 11 gm/dl in women were included. Exclusion criteria was when the hemoglobin concentration was less than 6 gm/dl, patients of thalassaemia, sickle cell anemia, aplastic anemia, haemolytic anemia, lead poisoning, sideroblastic anaemia, malignancies, congenital absence of iron binding protein, hereditary spherocytosis and any association of severe complication. Blood hemoglobin level becomes less than 5 gm/dl during the course of treatment, any other acute

illness, severe untoward effect, and not willing to continue was followed in discontinuation criteria.

Drugs Selection

Both drugs Dhatri louha [11] (Table 1) and Novayas louha [12] (Table 2) were purchased from local market, Jaipur. Starch capsules were collected from National Institute of Ayurveda Hospital, Jaipur, India.

Each 250 mg tablet conations				
Sl. No.	Botanical name	Local name	Part used	Amount
01	<i>Emblica officinalis</i>	Amla	Fruit	142.85 mg
02	<i>Louha Bashma</i>	Louha	-	71.42 mg
03	<i>Glycyrrhiza glabra L.</i>	Mudujasthi	Stem	35.71 mg

Table 1: Composition and concentration of Dhatri louha

Each 250 mg tablet conations				
Sl. no.	Botanical name	Local name	Part used	Amount
01	<i>Emblica officinalis</i>	Amla	Fruit	13.88 mg
02	<i>Terminalia chebula</i>	Hartaki	Fruit	13.88 mg
03	<i>Terminalia bellerica</i>	Bhibitak	Fruit	13.88 mg
04	<i>Zinziber officinale</i>	Adrak	Rhizome	13.88 mg
05	<i>Piper longum</i>	Pippali	Fruit	13.88 mg
06	<i>Piper nigrum</i>	Morich	Fruit	13.88 mg
07	<i>Plumbago zeylanica</i>	Chitrak	Bark	13.88 mg
08	<i>Cyperus rotundus</i>	Musta	Rhizome	13.88 mg
09	<i>Emblica ribes</i>	Bidang	Fruit	13.88 mg
10	<i>Louha bashma</i>	Louha	-	125 mg

Table 2: Composition and concentration of Novayas louha

Grouping and Administration of Drug

Randomly patients were divided into Group 1 or control Group, Group 2 and Group 3. Each group contained 10 numbers of patients. Group-1 or placebo control group was received one starch capsule daily per orally for 30 days. In Group 2 and Group 3 was administered Dhatri louha and Novayas louha in dose of 250 mg respectively twice a day for 30 consecutive days. During the experimental period, proper diet and counseling was followed according to Ayurvedic literature.

Assessment Criteria

Before and after treatment blood samples were collected for hemoglobin concentration (Hb%), packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH) and mean corpuscular hemoglobin concentration (MCHC) and it was determined at the central laboratory of National Institute of Ayurveda Hospital, Jaipur.

Ethical Consideration

Institutional Ethics Committee's (IEC) decision was followed throughout the study especially consent, sensitive issue, confidentiality, the privacy and safety of the subjects were protected throughout the processes.

Statistical Analysis

Numerical data obtained from this study were expressed as the mean value \pm standard error of mean. Differences before and after treatment in different groups were analyzed by using paired 't' test. The significant level was followed at least $p < 0.05$ confidence levels.

Results

Table 3 showed that before treatment the mean hemoglobin concentration was 9.64, 9.28, and 8.89 gm/dl in Group 1, Group 2 and

Group 3 respectively. After completion of treatment the hemoglobin concentration was significantly ($p < 0.05$) increased 10.83, and 10.51 gm/dl in Group 2 and Group 3 respectively when compared with

before treatment but Group 1 was showed gradually decreased hemoglobin level after 30 days of treatment.

Parameters	Group 1		Group 2		Group 3	
	Before treatment (Mean \pm SEM)	After treatment (Mean \pm SEM)	Before treatment (Mean \pm SEM)	After treatment (Mean \pm SEM)	Before treatment (Mean \pm SEM)	After treatment (Mean \pm SEM)
Hb (gm/dl)	9.64 \pm 0.35	08.92 \pm 0.42	9.28 \pm 0.34	10.83 \pm 0.32*	8.98 \pm 0.39	10.51 \pm 0.53*
PCV (%)	30.48 \pm 0.95	28.27 \pm 0.75	29.65 \pm 0.73	35.19 \pm 1.11*	28.91 \pm 0.84	38.66 \pm 1.29*
MCV(fl)	75.20 \pm 1.88	72.70 \pm 1.61	75.50 \pm 1.45	81.10 \pm 1.59*	75.80 \pm 1.30	79.50 \pm 2.00
MCH (pg)	23.90 \pm 0.87	23.40 \pm 0.80	22.50 \pm 0.70	27.80 \pm 0.69*	23.60 \pm 0.90	28.90 \pm 0.43*
MCHC (gm %)	27.40 \pm 0.45	27.80 \pm 0.89	29.10 \pm 0.62	30.90 \pm 1.06	27.90 \pm 1.02	32.10 \pm 0.86*

Note: Values are mean \pm SEM in each group and * $p < 0.05$ confidence levels

Table 3: Effect of Drugs on different Hematological parameters in patients of Iron deficiency Anaemia

It was also showed that Group 2 was more improvement than Group 3. Before treatment the PCV level was 30.48%, 29.65% and 28.91% in three respective groups. End of treatment it was found significant improvement in Group 2 and Group 3. On the other hand no improvement showed in Group 1. Among the groups the MCV was significant changed in Group 2 after treatment. The MCH was 23.90, 22.50 and 23.60 pg before treatment in Group 1, Group 2 and Group 3 respectively. After completion of treatment it was also significantly increased in both Group 2 and Group 3 and the level was 27.80 in Group 2 and 28.90 in Group 3. Group 3 was showed the significant change of the MCHC after completion of treatment.

Discussion

Iron is an important element in human metabolism [13]. It plays a central role in erythropoiesis and involved in many other intracellular processes in all the tissues of the body. After 30 days of treatment the results showed that the Hb, PCV, MCV, MCH and MCHC were gradually decreased in Group 1. Because in Group 1 it was administrated non iron containing substance. On the other hand in Group 2 and Group 3 the level of hemoglobin concentration, PCV, and MCH were significantly ($p < 0.05$) increased. The MCV was only increased in Group 2 and the MCHC in Group 3. It may have due to hemopoietic effect of Dhatri louha and Novayaas louha. Because Dhatri louha and Novayaas louha contains the common active ingredients *Emblica officinalis*, *Zinziber officinale*, *Louha Bashma*. *Emblica officinalis* is widely used in the Indian system of medicine and that increase the defense mechanism body. It is the richest source of vitamin C or ascorbic acid which helps in absorption of iron [14]. It is also useful as general tonic, laxative, liver tonic, stomachic, restorative, alterative, digestive. *Zingiber officinale* consists of protein, fat, carbohydrate, thiamin, riboflavin, nicotinic acid, calcium, iron and phosphorus. These components of ginger may facilitate the better absorption of iron [15]. *Lauha bhasma* is commonly used in different Ayurvedic preparations as incinerated form of iron and is indicated for different diseases particularly anaemia. It is already reported that *Lauha bhasma* has significant haematinic and haemoglobin regeneration efficiency in comparison to control and standard ferrous sulphate containing drug [16] *Novayas louha* also contained *Glycyrrhiza glabra* [17] *Piper longum* [18] *Terminalia belerica* [19]

Plumbago zeylanica [20] and *Cyperus rotundus* traditionally these plants are used in various diseases including anaemia. Some of them individually reported for the treatment of anaemia. They contain organic matter like ascorbic acid, sugars, amino acids, organic acids, which also helps for better absorption of non heme iron. Another component *Emblica ribes* is responsible for antihelminthic activity [21] that can prevent the anaemia because worm infestation is one of the main causes of anaemia in Indian subcontinent. In Ayurvedic pharmacology the maximum contents of both formulations have sheeta guna and sheeta virya and param raktavridhikar in karma that's why they are hematinic. Thus, it can be say that Dhatri louha and Novayaas louha are effective preparation for the treatment of iron deficiency anaemia.

Conclusion

In conclusion it is apparent that two Ayurvedic preparations are effective, well tolerated and clinically safe for correction of iron deficiency anemia. The results of this study indicate the improving nutritional anemia which needs to be ascertained a larger scale in multi-centre study.

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