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Research Article

"A COMPARATIVE CLINICAL STUDY OF VIDANGADI LOUHA & HAMSA MANDOORA ON *PANDU ROGA* (IRON DEFICIENCY ANEMIA) *W.S.R* TO THEIR HAEMATOLOGICAL & BIO CHEMICAL PARAMETERS".

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ABSTRACT

The purpose of clinical trial is primarily to establish efficacy and demonstrate freedom from unwanted side effects in human. Appropriate medicine plays a paramount role in the success of treatment as it is a main factor lying with the management of a disease. In other words there is directly proportional relationship between the success of treatment and the genuineness of medicine. Reports of clinical trial must be of such nature and sufficiently well documented to provide adequate evidence of efficacy and safety of the medicine, when administered to patients through proposed route in the dosage indicated clearly, the number of patients at the commencement and on completion of each trial, the range and mean dosage employed, the results obtained and any adverse reactions, which have been observed.

In the global campaign of health for all, promotion of proper nutrition is one of the eight elements of primary health care. Nutritional indicators have been developed to monitor health for all. Greater emphasis is now placed on integrating nutrition into primary health care systems whenever possible and formulation of national dietary goals to promote health and nutritional status of families and communities. Iron deficiency has been recognized as commonest nutritional deficiency disorder and a risk to the nation among top ten selected health risks, although this deficiency disorder has been described by the name *Panduroga* thousands of years ago in the Ayurvedic classics. These Ayurvedic classics have also recommended formulations of Louha (iron) for the management of this disease as best remedy.

Keywords: Anemia, hemoglobin, iron deficiency, *Pandu Roga*, serum ferritin

INTRODUCTION

A prominent diagnostic feature of *Pandu roga* is the pallor on the skin which occurs due to the quantitative and qualitative deficiency of *raktu dhatu* (blood tissue) caused either in the form of deficiency of hemoglobin and / or red blood cells (RBCs). Considering *Panduta* (pallor) as the predominant sign, the disease is termed as *Pandu roga*. The nearest correlation of iron deficiency anemia (IDA) can be made with *Pandu roga*, because of the predominance of *Panduta* or pallor in the whole body

Iron deficiency is a very common nutritional disorder worldwide and is known to affect approximately one third of the global population. While its incidence in affluent countries is low, the incidence of IDA in India is very high. According to National Family Health Survey (NFHS) III data, the incidence of anemia in urban is 71%, rural is 84%, and overall is 79%. Nutritional iron deficiency is the most common cause of anemia in India.

IDA is a very common disease prevalent in the society and side effects of oral allopathic iron preparations are very frequently encountered. With the aim that herbo-mineral medicines may be effective to manage IDA without any side effects, the present study was carried out to study the efficacy of an Ayurvedic herbo-mineral compounds Vidangadi louha & Hamsa mandoora with the application of modern parameters.

MATERIALS AND METHODS

Study design

A randomized, double-blind placebo-controlled clinical study was conducted in Patients suffering from IDA.

Selection of cases

For the study the patients having the clinical features of *Pandu roga* (IDA) were selected.

Inclusion criteria

- 60 cases were selected on randomized basis to avoid bias from **TTD Ayurvedic Dispensary (OPD), Tirumala.**
- Age group of patients was maintained in between 12 years to 60 years.
- A special detail clinical proforma has been prepared incorporating selected

symptoms and signs like "Hridayaspandana (palpitation), Shrama (fatigueness), Shwasa (breathlessness), Daurbalya (weakness) and Panduta (pallor) based on both Ayurvedic and Modern description. A detail history was taken and complete physical examination was carried out.

- Laboratory investigations like blood for complete haemogram, serum iron and TIBC (total iron binding capacity) were carried out and a level of the parameters was fixed for diagnosis of patients as follows.

Haemoglobin percentage :Below 11.5 g/dl

Mean corpuscular volume (MCV) :Below 76 fL

Serum iron (SI) :Below 35 µg/dl

Total iron binding capacity (TIBC) More than 400 µg/dl Present saturation of transferrin : Less than 10.

Criteria for exclusion of patients:

Some of the criteria fixed for exclusion of patients:

- Haemoglobin percentage : Below 5 g/dl
- Pregnant and lactating women
- Iron deficiency anemia (*Panduroga*) with cardiac complication, diabetes mellitus and malignancy.
- Iron deficiency anemia in a case of defective absorption. like patients of gastrectomy, gastro-jejunostomy, sprue syndrome.

Discontinuation criteria

- Blood hemoglobin level becomes less than 5 g/dL during the course of treatment
- Any other acute illness
- Parents not willing to continue
- Any severe untoward effect

Approval of institutional ethical committee

Institutional Ethics committee's approval was taken for the prospective, randomized, double-blind, placebo-controlled, parallel group clinical study.

Procurement of the drug

Both the trial drugs and the standard control were prepared in the attached Pharmacy of Gopabandhu Ayurveda Mahavidyalaya Puri Odisha. Both the trial drugs and standard control were of similar physical character and were packed in similar types of packing.

VIDANGADI LOUHA MSAMANDOORAM

S.NO	NAME OF THE INGREDIENT	PROPORTION
1	Louha churnam	1 part
2	Gomutram	8 parts
3	Vidanga	1 part
4	Haritaki	1 part
5	Amalaki	1 part
6	Vibhitaki	1 part
7	Musta	1 part
8	Devadaru	1 part
9	Sonti	1 part
10	Pippali	1 part
11	Maricha	1 part
12	Pippali moola	1 part
13	Chavya	1 part
14	Chitraka	1 part

S.NO	NAME OF THE INGREDIENT	PROPORTION
1	Mandoora churnam	1 part
2	Gomutram	8 parts
3	Vidanga	1 part
4	Haritaki	1 part
5	Amalaki	1 part
6	Vibhitaki	1 part
7	Musta	1 part
8	Devadaru	1 part
9	Sonti	1 part
10	Pippali	1 part
11	Maricha	1 part
12	Pippali moola	1 part
13	Chavya	1 part
14	Chitraka	1 part

STUDY PROTOCOL:

Total 60 patients were registered for the clinical trial and divided randomly into 3 groups, each containing 20 patients. Group-I and II were treated by VIDANGADI LOUHA and HAMSA MANDURA respectively. Group-III was treated by standard drug i.e. dried ferrous sulphate. The treatment schedule was continued for 30 days with twice daily doses of test drugs and standard drug, patients were also followed up for next 30 days. Unwanted effects of drugs, if any during the total period (60 days) were noted, laboratory investigation of blood and serum of each patient was carried out before commencement and after completion of treatment.

Haematological parameters studied :

Blood was collected for performing haematological tests like Haemoglobin percentage, total RBC count, Mean Corpuscular Volume, Mean Corpuscular Haemoglobin.

Biochemical parameters studied :

Serum was separated from blood and conducted tests for serum iron and total iron binding capacity. Biochemical parameters were estimated in photometer-5010 apparatus in biochemistry laboratory.

Grouping of patients :

Group	***Drug***	***Dose (mg/day)***
I	*VIDANGADI LOUHA*	125
II	*HAMSA MANDURA*	125
III (Standard	Dried ferrous sulphate	125

OBSERVATIONS AND RESULTS:

Effect of therapy on haematological parameters :

TABLE - 6.1

Effect of tests and standard drug preparations on haemoglobin percentage in patients of '*Pandu* roga' (iron deficiency anaemia)

Group	Dose (mg/day)	Haemoglobin Content (g/dL)				'P'
		Before Treatment	After Treatment	Change		
		Mean ± SEM	Mean ± SEM	Mean ± SEM	In (%)	
Ferrous sulphate	125	10.4 ± 0.7	11.2 ± 0.9↑	0.9 ± 0.2↑	08.6↑	<0.01**
VIDANGADI LOUHA	125	09.4 ± 0.7	10.5 ± 0.7↑	1.1 ± 0.2↑	11.3↑	<0.01**
HAMSA MANDURA	125	10.3 ± 0.5	12.0 ± 0.5↑	1.7 ± 0.2↑	16.9↑	<0.001**

↑ = Increase, ** = Highly significant

The data pertaining to the effect of tests and standard drugs on haemoglobin percentage have been summarized in Table-6.1. A highly significant increase in haemoglobin percentage was observed in both the test drug groups and standard control group. It would be pertinent to note here that the percentage of increase in HAMSA MANDURA treated group is almost

double in comparison to reference standard group.

TABLE - 6.2

Effect of tests and standard drug preparations on total RBC count in patients of '*Pandu* roga' (iron deficiency anaemia)

Group	Dose (mg/day)	Total RBC Count (10^6/ul)				'P'
		Before Treatment	After Treatment	Change		
		Mean ± SEM	Mean ± SEM	Mean ± SEM	In (%)	
Ferrous sulphate	125	4.71 ± 0.2	4.68 ± 0.2↓	0.03 ± 0.1↓	0.64	>0.5
VIDANGADI LOUHA	125	4.27 ± 0.3	4.28 ± 0.2↑	0.01 ± 0.1↑	0.09	>0.5
HAMSA MANDURA	125	4.52 ± 0.2	4.64 ± 0.2↑	0.12 ± 0.7↑	2.43	>0.1

↑ = Increase, ↓ = Decrease

A minute alteration in total RBC count was observed in all the groups, in standard control group, it was found to be decreased and was found to be increased in both test drug treated groups.

TABLE - 6.3

Effect of tests and standard drug preparations on Mean Corpuscular Volume in patients of '*Pandu* roga'(iron deficiency anaemia)

Group	Dose (mg/day)	Mean Corpuscular Volume (MCV) (fL)				'P'
		Before	After	Change		
		Mean ±	Mean ±	Mean ±	In (%)	
Ferrous sulphate	125	70.7 ± 3.6	75.5 ± 3.5↑	4.8 ± 0.6↑	6.8↑	<0.001**
VIDANGADI LOHADI	125	70.2 ± 3.3	76.4 ± 1.5↑	6.2 ± 2.0↑	8.8↑	<0.02*
HAMSA MANDURA	125	71.0 ± 1.0	76.2 ± 1.0↑	5.2 ± 1.0↑	7.3↑	<0.001**

↑ - Increase, * = Significant, ** = Highly significant

A statistically highly significant increase in Mean Corpuscular Volume was observed in both standard control and *HAMSA MANDURA* treated groups, whereas a statistically significant increase was found in *VIDANGADI LOHA* treated group.

TABLE - 6.4

Effect of tests and standard drug preparations on Mean Corpuscular Haemoglobin in patients of '*Pandu* roga' (iron deficiency anaemia)

Group	Dose (mg/day)	Mean Corpuscular Haemoglobin (pg)				'P'
		Before Treatment	After Treatment	Change		
		Mean ± SEM	Mean ± SEM	Mean ± SEM	In (%)	
Ferrous sulphate	125	22.1 ± 1.6	23.9 ± 1.6↑	1.8 ± 0.5↑	08.1↑	<0.01**
VIDANGADI LOUHA	125	22.3 ± 1.3	24.4 ± 0.7↑	2.1 ± 0.8↑	09.4↑	<0.05*
HAMSA MANDURA	125	22.7 ± 0.5	25.9 ± 0.5↑	3.2 ± 0.4↑	14.1↑	<0.001**

↑ = Increase, * = Significant, ** = Highly significant

A statistically highly significant increase in Mean Corpuscular Haemoglobin was observed in both standard control and *HAMSA MANDURA* treated groups, whereas statistically significant increase was found in *VIDANGADI LOHA* treated group.

TABLE - 6.5

Preparations on serum iron level in patients of '*Pandu* roga' (irondeficiency anaemia)

Group	Dose (mg/day)	Serum Iron (µg/dL)				'P'
		Before Treatment	After Treatment	Change		
		Mean ± SEM	Mean ± SEM	Mean ± SEM	In (%)	
Ferrous sulphate	125	31.3 ± 1.5	39.0 ± 1.3↑	07.6 ± 0.8↑	24.4↑	<0.001**

VIDANGADI LOUHA	125	29.1 ± 3.1	38.8 ± 2.8↑	09.2 ± 2.1↑	31.6↑	<0.01**
HAMSA MANDURA	125	29.0 ± 1.5	40.1 ± 1.5↑	11.1 ± 1.7↑	38.1↑	<0.001**

↑ = Increase ** = Highly Significant

A statistically highly significant increase in serum iron level was observed in all the groups.

TABLE - 6.6

Effect of tests and standard drug preparations on total iron binding capacity in patients of '*Pandu* roga' (iron deficiency anaemia)

Group	Dose (mg/day)	ıding Capacity (TIBC) (µg/dL)				'P'
		Before Treatment	After Treatment	Change		
		Mean ± SEM	Mean ± SEM	Mean ± SEM	In (%)	
Ferrous sulphate	125	434.9 ± 19.0	402.9 ± 16.0↓	32.0 ± 4.8↓	07.4↓	<0.001**
Vidangadi lo	125	474.3 ± 21.9	436.1 ± 17.1↓	38.1 ± 7.1↓	08.0↓	<0.01**
Hamsa	125	446.0 ± 12.0	390.9 ± 13.6↓	55.1 ± 9.7↓	12.4↓	<0.01**

↓ = Decrease, ** = Highly significant.

The data of effect of tests and standard drugs on total iron binding capacity (TIBC) have been summarized in Table - 6.6 A statistically highly significant decrease in total iron binding capacity was found in all the groups.

TABLE - 6.7

Effect of tests and standard drug preparations on percent saturation of transferrin in patients of '*Pandu* roga'(iron deficiency anaemia)

	Dose	Percent Saturation of Transferrin (%)			
		Before Treatment	After Treatment	Change	

Group	(mg/day)	Mean ± SEM	Mean ± SEM	Mean ± SEM	In (%)	'P'
Ferrous sulphate	125	7.3 ± 0.5	9.8 ± 0.5↑	2.5 ± 0.1↑	34.2↑	<0.001**
VIDANGADI LOUHA	125	6.3 ± 0.7	9.1 ± 0.9↑	2.8 ± 0.5↑	44.4↑	<0.01**
HAMSA MANDURA	125	6.5 ± 0.4	10.3 ± 0.5↑	3.8 ± 0.5↑	58.5↑	<0.001**

↑ = Increase, ** = Highly significant

The data revealing the effect of tests and standard drugs on percent saturation of transferrin have been presented in Table - 6.7. A highly significant increase in percent saturation of transferrin was observed in all the groups.

Overall effect of therapy on basis of laboratory investigations:

TABLE - 6.8

Effect of tests and standard drug preparations in patients of '*Pandu* roga'(iron deficiency anaemia)

Group	Dose (mg/day)	Improvement (%)			
		Marked Improvement	Moderate Improvement	Mild Improvement	No Change
Ferrous sulphate	125	00.0	50.0	50.0	00
VIDANGADI LLOHA	125	14.4	42.8	42.8	00
HAMSA MANDURRA	125	28.7	57.1	14.4	00
Overall effect	-	13.6	50.0	36.4	00

The data pertaining to the effect of tests and standard drugs on improvement in patients on the basis of laboratory investigation have been summarized in Table -6.8. Moderate improvement in 50% patients and

mild improvement in another 50% of patients were observed in standard control group. Marked improvement in 14.4% of patients, moderate improvement in 42.8% of patients and mild improvement in 42.8% of patients were found in *VIDANGADI LOUHA* treated group. Marked improvement in 28.7% of patients, moderate improvement in 57.1% of patients and mild improvement in 14.4% of patients were noticed in *HAMSA MANDURA* treated group. Out of 60 patients registered, 52 patients have completed the treatment schedule, among them, marked improvement in 13.6% of patients, moderate improvement in 50% of patients and mild improvement in 36.4% of patients were observed on the basis of improvement in haemoglobin percentage, serum iron and total iron binding capacity.

DISCUSSION

Families of poor income group are unable to afford proper diet due to improper and imbalanced diet. As per the WHO report iron deficiency is the most common among groups of low socio-economic status. The disease *Pandu roga* is equally prevalent in both vegetarians and non-vegetarians. The disease is more prevalent in the *Prakriti* dominant in *Pitta*. As *Pandu roga* is *Pitta* dominant *tridoshaja vikara* (disease caused due to anomalous behaviour of all the three doshas) and under-nutrition is commonly found in *Vata* dominant persons. So probably this might be the reason of majority of patients being of *Vata-Pitta Prakriti* group in the present study. *Mandagni* and *Madhyama koshtha* are observed in maximum patients. Consuming insufficient diet due to *Mandagni* leads to malnutrition, the root cause of disease. According to Ayurveda abnormal function of Agni is the root cause of all diseases. *Madhyama Koshtha* showing dominance of *Kapha* leads to improper digestion, which is the important cause of any disease. *Kapha Dosha* is predominant during childhood period and *kapha dosha* also plays an important role in the pathogenesis of the disease.

After 30 days treatment with the trial drug, highly significant improvement was observed in the clinical features of IDA with P value < 0.001. After 20

days of medication comparatively faster improvements were observed in the clinical features such as pallor, anorexia, weakness, fatigue, irritability. Clinical features of *Pandu roga* (IDA) are mainly due to quantitative and qualitative reduction of Hb and less oxygen supply in the tissues. 1 g% hemoglobin, when fully saturated, combines with 1.34 ml of oxygen, therefore, hemoglobin concentration is an index of oxygen carrying capacity of blood. With the trial drugs therapy hemoglobin status improves, body tissues get adequate oxygen, body metabolism improves, and ultimately relief in clinical symptoms is observed.

The present clinical study shows the hematinic potential of *Vidangadi louha & Hamsa mandoora*, It is evident that the treatment of iron deficiency anemia with *Hamsa mandoora* shows statistically significant increase of hematologic values, such as blood Hb%, total RBC, PCV, MCV, MCH, and so on. Blood hemoglobin level was improved significantly with a mean increase of 1.94 g/dL in 20 days (8.52-10.46 g/dL, P <0.001) and 3.33 g/dL in 30 days (8.52-11.85 g/dL, P<0.001). After 30 days treatment in the trial groups, Hb was increased by 11.3% in *Vidangadi louha group and 16.9% in Hamsa Mandoora group.*

Hamsa Mandoora is more effective than _Vidangadi louha._

Vidangadi louha & Hamsa mandoora are Ayurvedic herbo-mineral drugs containing same combination except louha basma in *Vidangadi louha & Mandoora basma in Hamsa mandoora*. The trial drugs contains herbal drugs like *Triphala*, which is rejuvenative; *Trikatu*, which is an appetizer; and *Trimada*, which is digestive. Herbal ingredients in the trial drug may increase the bio-availability of *Mandura bhasma and louha bhasma* which are important contents of the formulation. About 10% of iron in an average Indian diet is normally absorbed. More is absorbed during deficiency states. Iron deficient state absorbs about 30% of dietary iron.

Effectiveness of *Haritaki*, *Mandura Bhasma*, and *Louha Bhasma* to increase blood hemoglobin level has been proved scientifically by previous research studies. *Amalaki (Emblica officinalis)* is richest source of Vitamin C, which helps in absorption of iron.

Vitamin C reduces ferric iron to ferrous iron, which remains soluble even at neutral pH and is better absorbed. *Amalaki* enhances the production of RBCs and increases immunity in the body. *Pippali* is a proved drug to increase bio-availability. *Triphala* have *Anulomana* property and counteract the constipative effect of iron compounds like *Louha Bhasma* and *Mandura Bhasma*.

Long-term treatment is needed for the treatment of IDA and *Hamsa mandoora* can be prescribed for long-term period without any adverse effect in patients.

CONCLUSIONS

Vidangadi louha & Hamsa mandoora have been subjected to a clinical study on patients suffering from IDA. They contain iron (*Mandura Bhasma* and *Louha Bhasma*) and herbal ingredients (*Triphala*, *Trikatu*, and *Trimada*). Herbal ingredients present in the trial drug may increase the bio-availability of iron. Hematinic action of *Hamsa mandoora* may be due to the presence of iron contents of good bio-availability. The present clinical study clearly indicates that the herbo-mineral formulation *Hamsa mandoora* is an effective, well-tolerated, and clinically safe formulation for the management of IDA than *Vidangadi louha*.

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