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A Controlled Comparative Clinical Study of Lohamritam in the Management of *Pandu* (w.s.r. to Iron Deficiency Anaemia)

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ABSTRACT

INTRODUCTION

Pandu is a *pitta* dominant *tridoshaja* disorder affecting the whole body. Iron deficiency anemia can result from inadequate iron intake, decreased iron absorption, increased iron demand or increased iron loss.

MATERIAL AND METHODS

Total 30 patients of *pandu* were registered in two groups. Patients of group A were treated with *lohamritam:* 1 tablet of 250 mg twice a day on empty stomach with honey for 8 weeks of period. Patients of group B were treated with ferrous sulphate: 1 tablet of 200 mg twice a day with lemon water on empty stomach for 8 weeks of period. Signs and symptoms were assessed with the help of specially prepared grade scores. Haematological parameters were also assessed.

RESULTS

Patients of group A who were treated with *lohamritam* oral medicaments have same relief compared to the patients of group B who consumed oral medicaments of ferrous sulphate. It was tested with un-paired 't' test.

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CONCLUSION

Lohamritam is effective therapy for the management of *pandu* vis-a-vis iron deficiency anemia. Considering the level of significance, *lohamritam* is equally effective when compared with the ferrous sulphate, already established modern conventional medicine for iron deficiency anemia.

KEYWORDS

Pandu, Iron deficiency anemia, Lohamritam, Ferrous sulphate

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INTRODUCTION

Pandu is *pitta* dominant *tridoshaja* disorder affecting the whole body. When the *pitta pradhana doshas* are aggravated in the *dhatus*, then the *dhatus* get affected, with the result they become *shithila* and thereafter, the *varna, bala, sneha* and other properties of *ojas* get exceedingly reduced on account of the vitiation of *doshas* and *dushyas*. So, the patient becomes *nihsara* (low quality of the tissues) and *shithilendriya* (feeling of lack of energy in sense organs) and suffers from *vaivarnya* (discolouration)[1]. *Pandu roga* is a disease characterized by pallor of body which similar with cardinal sign of anaemia in modern science, anemia is one of the common blood disorders. Iron deficiency anemia is the most common type of anemia[2]. It develops due to inadequate availability of iron for hemoglobin synthesis. According to the World Health Organization (WHO), there are two billion people with anemia in the world and half of the anemia is due to iron deficiency[3].

Iron preparation provides satisfactory result in iron deficiency anemia. But usually iron preparations have some common side effects like abdominal pain, nausea and either constipation or diarrhea[4]. *Lohamritam* is an *ayurvedic* preparation which contains *loha bhasma* (ultrafine ash of iron) along with other *ayurvedic* herbal medicines. This *ayurvedic* iron preparation, due to its ingredients may prevent the common hazards of oral iron therapy like gastrointestinal upset, abdominal discomfort, constipation, iron intolerance etc. *Lohamritam* is a combination of eleven drugs (*Musta, guduchi, pippali, yashtimadhu, chitraka, sunthi, haritaki, bibhitaka, amalaki, vidanga* and *loha bhasma*) most of which have actions like *vata-kaphahara, tridoshahara, dipana-pachana* and dominance of *usna* property. Thus it acts against *ama* formation and corrects the *agni* and also have properties like *anulomaka, srotovibandhahara, rasayana* and *yakriduttejaka*, can help to clear the *srotasas* which results in utility of *rasa*. Moreover *amalaki*, which is a well-known drug for *pandu roga*, contains vitamin C which promotes iron absorption. Hence, medicine increases the *agnivyapara* at its optimum level which breaks the pathogenesis of *pandu roga*.

AIMS AND OBJECTIVES

1. To find out the effect of *lohamritam* in the patients of *pandu* (iron deficiency anemia) by observing the changes in the signs and symptoms as well as laboratorial investigations.

2. To compare the effectiveness of *lohamritam* and ferrous sulphate in the patients of *pandu* (iron deficiency anemia).

MATERIALS AND METHODS

Selection of the patients

All the patients who fulfilled the inclusion criteria were selected from out-patient department of kayachikitsa and randomly divided in to two groups. The study obtained Institutional Ethics Committee clearance (JSAM/IECHR/37/12-2015) and registered at Clinical Trial Registry of India (CTRI/2016/02/006667). A written informed consent from each patient was taken before enrolling in the clinical trial.

Inclusion criteria

1. Patients having clinical signs and symptoms of *pandu*.
2. Patients with hemoglobin level between 7 to 10 gm %
3. Patients between 18 to 60 years of age.

Exclusion criteria

1. Patients having thalassemia, sickle cell anemia, leukemia and aplastic or hypoplastic anemia.
2. Patients with bleeding piles.
3. Patients associated with cardiac disease, diabetes mellitus, chronic kidney diseases, cirrhosis of liver, nephrotic syndrome.

Investigations

Level of hemoglobin with red blood cell count, serum ferritin, serum iron, total iron binding capacity, packed cell volume, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration and routine urine examination were also recorded in all the patients before and after treatment.

Treatment protocols

GROUP – A

Lohamritam[5]

Patients of group A were treated with the *lohamritam* for 8 weeks period.

- *Matra* – 250 mg
- *Kala* – After meal
- *Anupana- Madhu*
- Duration- 2 time/day
- Route of administration- Oral

GROUP - B

Ferrous sulphate

Patients of group B were treated with the tablet of ferrous sulphate for 8 weeks period.

- *Matra* –200 mg
- *Kala* –After meal
- *Anupana* - Lemon water
- Duration- 2 times/day
- Route of administration- Oral

Criteria for assessment:

Assessment was done on the basis of haematological parameters like level of

hemoglobin with red blood cell count, serum ferritin, serum iron, total iron binding capacity, packed cell volume, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration and routine urine examination. Signs and symptoms were assessed with the help of specially prepared grade scores.

The grade score pattern is shown in table no.1

Table 1 Criteria for assessment

Signs and symptoms	**Grade score**				
	0	**1**	**2**	**3**	**4**
Pallor: The score was decided on the basis of pallor present in skin, nails, conjunctiva, tongue and palms	Absent	In any two of these	In any three of these	In any four of these	In any five of these
Weakness	Not Present	After heavy work, relieved soon & tolerated	After moderate work, relieved later & tolerated	After little work, relieved after that	After little work, relieved after that but not tolerated
Palpitation	Not Present	After heavy work, relieved soon & tolerated	After moderate work but relieved after that & tolerated	After little work but relieved after that & tolerated	After little work, relieved after that but not tolerated
Orbital oedema	Absent	Mild	Moderate	Marked	Severe
Dyspnoea on exertion	Not present	After heavy work, relieved soon & tolerated	After moderate work but relieved after that & tolerated	After little work but relieved after that & tolerated	After little work, relieved after that but not tolerated
Anorexia	Normal desire for food	Eating timely without much desire	Desire for food, little late than normal time	Desire for food only after long intervals	No desire at all

Fatigue	No fatigue	Occasional fatigue but patient is able to do usual work	Continuous fatigue but patient is able to do usual work	Continuous fatigue which hampers routine work	Patient is unable to do any work
Tastelessness	Normal taste of mouth	Occasional sensation of unpleasant taste	Continuous sensation of unpleasant taste but vanishes after eating something	Continuous mild sensation of unpleasant taste which persists even after eating	Severe unpleasant taste throughout the day
Giddiness	Absent	Occasional	Frequently	Regular	Constant

Criteria for the assessment of overall effect of therapy:

1. Improvement < 25% – no relief
2. Improvement >= 25% up to 50%- mild relief
3. Improvement >= 50% up to 75%- moderate relief
4. Improvement >= 75% up to 100%- marked relief
5. 100% improvement- complete relief

For the overall assessment, the subjective criteria and objective criteria were given equal (i.e. 50%) weightage. For assessment of subjective and objective criteria each, the average of all the symptoms (in subjective criteria) and signs (in objective criteria) were considered.

Statistical analysis: Obtained data were statistically analyzed using un-paired t-test.

Table 2 Comparative effect of treatment on signs and symptoms, and investigations in patients of both the groups

Sign-symptoms and investigations	Mean score		Overall S.D.	Degree of freedom	t value	P value
	Group A	Group B				
Pallor	1.23	0.6	0.71	21	2.09	P<0.05
Weakness	1.75	1.57	0.54	28	0.89	p>0.05
Dyspnoea on exertion	1.16	0.89	0.30	20	1.43	p>0.05
Fatigue	1.16	1.00	0.69	10	0.39	p>0.05
Giddiness	1.25	1.14	0.57	13	0.36	p>0.05
Anorexia	1.71	1.17	0.75	11	1.28	p>0.05
Orbital oedema	1.33	0.80	0.49	06	1.46	p>0.05

HB	1.73	1.31	0.92	28	1.23	p>0.05
RBC	0.25	0.22	0.30	28	0.27	p>0.05
SERUM FERRITIN	13.83	12.09	13.11	28	0.36	p>0.05
SERUM IRON	29.31	26.64	26.20	28	0.27	p>0.05
TIBC	43	35.65	38.25	28	0.52	P>0.05
PCV	2.4	2.17	2.96	28	0.21	p>0.05
MCV	4.73	4.61	5.56	28	0.05	p>0.05
MCH	1.71	1.05	1.83	28	0.98	p>0.05
MCHC	1.58	1.5	2.55	28	0.08	p>0.05

RESULTS AND DISCUSSION

Table-2 As seen in table no.2 all the signs and symptoms except pallor were statistically insignificant when each sign or symptom of patients of group A was compared with the patients of group B. All the laboratory parameters were statistically insignificant when each parameter of patients of group A was compared with the patients of group B.

Table 3 Effect of treatment on signs and symptoms and investigations in the patients of group A

Sign-symptoms and investigations	**N**	**Mean value**		**D**	**Relief in %**	**S.D. ±**	**S.E. ±**	**T value**	**P value**
		BT	**AT**						
Pallor	13	2.16	0.84	1.23	59.25	0.72	0.20	6.12	p<0.001
Weakness	16	2.12	0.37	1.75	82.35	0.57	0.14	12.12	p<0.001
Dyspnoea on exertion	13	1.61	0.53	1.16	66.66	0.27	0.07	14	p<0.001
Fatigue	06	1.83	0.67	1.16	63.63	0.75	0.30	3.79	p<0.01
Giddiness	08	1.75	0.5	1.25	71.42	0.71	0.25	05	p<0.001
Anorexia	07	1.86	0.14	1.71	92.30	0.75	0.28	06	p<0.001
Orbital oedema	03	1.67	0.33	1.33	80	0.57	0.33	04	p<0.05
HB	16	8.67	10.40	1.73	19.95	0.99	0.25	6.97	p<0.001
RBC	16	3.73	3.98	0.25	6.79	0.24	0.06	4.14	p<0.001
S. Ferritin	16	7.97	21.80	13.83	173.4	14.48	3.62	3.81	p<0.001
S. iron	16	54.63	83.93	29.31	53.66	20.78	5.19	5.64	p<0.001
TIBC	16	345.9	302.93	43	12.42	32.11	8.02	5.35	p<0.001
PCV	16	27.28	29.68	2.4	8.79	2.27	0.57	4.22	p<0.001
MCV	16	72.9	77.63	4.73	6.49	6.21	1.55	3.05	p<0.01
MCH	16	23.58	25.3	1.71	7.26	2.22	0.55	3.08	p<0.01
MCHC	16	31.26	32.85	1.58	5.05	2.54	0.63	2.48	p<0.05

Table-3 In group A maximum i.e. 92.30% relief was observed in anorexia, followed by 82.35% and 80% relief was found in weakness and orbital oedema. In giddiness,

dyspnea on exertion, fatigue and pallor; 71.42%, 66.66%, 63.63% and 59.25% relief was found and among the objective criteria, maximum i.e. 173.4% relief was observed in serum ferritin followed by 53.66% relief in serum iron. 19.95% and 12.42% relief was found in hemoglobin (HB) and total iron binding capacity (TIBC). 8.79%, 7.26%, 6.79%, 6.49% and 5.05% relief was found in packed cell volume (PCV), mean corpuscular hemoglobin (MCH), red blood cell count (RBC), mean corpuscular volume (MCV), mean corpuscular hemoglobin concentration (MCHC) respectively.

Table no-4 In group B maximum i.e. 80% relief was observed in giddiness, followed by 78.57% and 75% relief in weakness and fatigue. In dyspnea on exertion, anorexia, orbital oedema and pallor; 66.67%, 63.63%, 50% and 42.85% relief was found and among the objective criteria, maximum i.e. 243.2 % relief was observed in serum ferritin followed by 45.38% relief in serum iron. 14.42% and 9.73% relief was found in

Table 4 Effect of treatment on signs and symptoms and investigations in the patients of group B

Signs and symptoms	N	Mean value		D	Relief in %	S.D. ±	S.E. ±	T value	P value
		BT	AT						
Pallor	10	1.4	0.8	0.6	42.85	0.69	0.22	2.71	p<0.05
Weakness	14	2.0	0.43	1.57	78.57	0.51	0.14	11.44	p<0.001
Dyspnoea on exertion	09	1.33	0.44	0.89	66.67	0.33	0.11	08	p<0.001
Fatigue	06	1.33	0.33	1.0	75	0.63	0.26	3.87	p<0.01
Giddiness	07	1.42	0.28	1.14	80	0.38	0.14	08	p<0.001
Anorexia	06	1.83	0.67	1.17	63.63	0.75	0.31	3.79	p<0.01
Orbital oedema	05	1.6	0.8	0.8	50	0.45	0.2	04	p<0.01
HB	14	8.87	10.18	1.31	14.72	0.85	0.23	5.75	p<0.001
RBC	14	3.78	4.00	0.22	5.81	0.35	0.09	2.32	P<0.01
S. Ferritin	14	4.97	17.06	12.09	243.2	11.32	3.02	3.99	p<0.001
S. Iron	14	58.71	85.35	26.64	45.38	31.32	8.37	3.18	p<0.01
TIBC	14	366.2	330.5	35.65	9.73	44.29	11.83	3.01	p<0.01
PCV	14	27.98	30.15	2.17	7.75	3.61	0.96	2.25	p<0.05
MCV	14	72.71	77.32	4.61	6.34	4.71	1.25	3.66	p<0.05
MCH	14	26.27	27.32	1.05	3.99	1.27	0.34	3.09	p<0.01
MCHC	14	31.52	33.03	1.50	4.76	2.55	0.68	2.19	P<0.05

hemoglobin (HB) and total iron binding capacity (TIBC). 7.75%, 6.34%, 5.81%, 4.76% and 3.99% relief was found in packed cell volume (PCV), mean corpuscular volume (MCV), red blood cell count (RBC), mean corpuscular hemoglobin concentration (MCHC), mean corpuscular hemoglobin (MCH) respectively.

Overall assessment of effect of treatment on 30 patients of *pandu*

Group A: 43.75 % patients belonged to the group of mild improvement. 37.5 % patients had moderate improvement and 18.75% had marked improvement. No any patient of group A was found in unchanged group.

Group B: 42.85% patients belonged to the group of mild improvement. 35.73% patients had moderate improvement. 14.28% had marked improvement and only one patient was found in unchanged group.

Discussion on the disease reveals that *pandu* (iron deficiency anemia) is *pitta* dominant *tridoshaja* disorder which affects *dhatus* with the result they become *shithila* and thereafter, the *varna*, *bala*, *sneha* and other properties of *ojas* get exceedingly reduced on account of the vitiation of *doshas* and *dushyas*. Most of the ingredients of drugs *lohamritam* have *katu rasa, laghu guna* and *usna virya* which useful for increasing *jatharagni* as well *dhatvagni* and also do *amapachana*. Correction of *jatharagni* and *dhatvagni* will provide adequate nourishment to all the *dhatus*. Moreover maximum drug have *dipana-pachana* properties they also correct the *agni* and the other ingredient have *rasayana* properties which help to correct the *pandu roga* and gives quick relief from symptoms and also increased the values of laboratory investigations. According to modern medicine, sign and symptoms of anemia can be corrected by ferrous sulphate; already established medicine for the anemia.

CONCLUSION

Lohamritam is effective therapy for the management of *pandu* vis-a-vis iron deficiency anemia. Considering the level of significance, it is also equally effective when compared with the ferrous sulphate, already established modern conventional medicine for iron deficiency anemia. However, according to the percentile relief, in some signs and symptoms, *lohamritam* is more effective than ferrous sulphate. Ferrous sulphate creates gastric discomfort as well as constipation in the patients which was not observed in the patients who consumed *lohamritam*. Hence, *lohamritam* is equally effective and safer than ferrous sulphate. This is an established fact that iron is

assailable only in certain chemical forms e.g. ferrous sulphate. In *lohamritam* iron is mostly in oxides and in elemental form. This is counter-evidence against this myth. Moreover the daily consumption of ferrous sulphate in the present study was 400 mg while in case of *lohamritam* the daily consumption of iron compounds was only 250mg. This is a valuable hint for further studies to establish the effectiveness of lower consumption of iron with better outcomes. This also leads towards an important point that even smaller amount of iron in combination of *ayurvedic dpiana* and *pachana* medicines may promote the assimilation better.

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