

An Observational Clinical Study of *Navayasalauha* Tablets w.s.r. to Iron Deficiency Anemia

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Abstract

Sanskrit word Pandu means *pale* or *Sweta Peet Varna*. The disease in which whole body becomes *pale* is called *Pandu roga*. The main cause of *Pandu roga* is related to diet. In short, *Pandu roga* is related to Anemia in modern system of medication. It is more resembles to Iron deficiency anemia. Insufficient dietary intake and improper absorption of iron are the causes of Iron Deficiency Anemia which presents with the significant symptoms such as feeling of weakness, tiredness, and shortness of breath, palpitations, *Koilonychia*, *Glossitis*, Dysphagia and altered sensation of taste. Allopathic iron preparations are gastric irritants and having common side effects like nausea, vomiting, constipation or diarrhea and black stool. Ayurvedic herbo mineral formulations are the better alternative to treat iron deficiency anemia. Navayasa loha, a herbo mineral compound contains loha bhasma as one of the ingredient mixed with other herbs. Loha bhasma helps to increase iron content in blood by its nano particulate size, better absorbs of iron and lesser side effect on GIT. Hence *Navayasa Lauha* was selected as an alternative medicine in iron deficiency anemia. The present work was carried out to check the effectiveness of *Navayasa Lauha* in iron deficiency anemic patient.

Keywords

Ayurveda, Clinical evaluation, Iron deficiency anemia, Navayasa Lauha , Pandu roga



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INTRODUCTION

Iron deficiency is the most predominant nutritional disease in all over the world. It is affecting about 2 billion people all over the world and significantly leads to death and disability of person. Decrease in number of RBCs and decrease in percentage of Hemoglobin in blood leads to a disease called anemia. Major cause of anemia is the deficiency of iron in blood. Iron deficiency leads to child mortality, maternal mortality, birth, morbidity, work productivity and child development.

As per the Ayurvedic system of medicine, disturbance in *pitta* prakruti causes anemia in body. Such condition in Ayurveda was described as a *Pandu roga*. It is a state of condition where natural girt losses with a sign of paralysis or weakness of both lower limbs. It is a *pitta pradana vyadhi* in which *rasa dhatu* and *rakta dahu* are mainly affected. The word Pandu is found in Rugveda which enlightens the facts that this diseases continuing since Vedic period. Based on symptoms of *Pandu roga*, *rasa dhatu* and *rakta dhatu* are not going to nurture due to additional intake of *pitta prakopaka ahara, vihara*⁽¹⁾.

Pandu roga is commonly known as Iron Deficiency Anemia and is characterized with symptoms such as feeling of weakness, tiredness, and shortness of breath, palpitations, *Koilonychia*, *Glossitis*, Dysphagia and altered sensation of taste. **Pitta** dosa is accountable for the preservation of food into heat, tissues and waste materials. It oversees digestion and metabolism from the cellular level to the tissue level, to that of the body as a whole.⁽²⁾

Oral and parenteral treatment of Anemia is available in allopathic system of medicines, but it is unsatisfactory due to many disadvantages associated with modern system of medicines such as nausea, abdominal pain, diarrhea, black stool, constipation etc. With the use of parenteral therapy for correction of iron deficiency causes hypersensitive reactions, hemolysis, hypotension, circulatory collapse, vomiting and sometimes muscular pain. In emergency, transfusion of blood raises hemoglobin up to 1 gm. with a single unit but needs more precaution and safety. Thus it is important to search a safer, cost effective and patient friendly therapy for anemia^(3,4).

Ayurvedic herbo mineral formulations are the better alternative to treat iron deficiency anemia. Loha is widely used in Ayurveda for the management of *Pandu*, *shotha*, *kamala* etc. Loha is a hard metal and used in form of purified bhasma for better absorption of it. Loha bhasma helps to increase iron content in blood by its nano particulate size, better absorbs of iron and lesser side effect on GIT^(5,6).

Navayasa Lauha , a herbo mineral Ayurvedic formulation contains loha bhasma as one of the ingredients. Navayasa loha is widely used as a hematinic agent (*Panduhara*) apart from its other indications in *Kushta*, *Kamala*, *Pramehapidika*, *Shotha* etc⁽⁷⁾. Hence it is selected as an alternative medicine in iron deficiency anemia. To ascertain the claim of the traditional medicine and to clinically evaluate effectiveness of Navayasa loha it is necessary to do observational clinical study of Navayasa loha with special reference to Iron deficiency anemia.

Institutional ethics committee of Ayurvedic College of P. D. Patel Ayurvedic Hospital, teaching hospital of J.S. Ayurveda College, Nadiad has approved the protocol for the said clinical study of *Navayasa Lauha* .

Main objective of conducting clinical trial of *Navayasa Lauha* is to check the hematinic activity of it. Increased hemoglobin content in blood was measured as a main parameter to check its hematinic activity.

MATERIALS AND METHODS

An observational clinical study has been conducted in patient suffering from iron deficiency anemia.

Selection of Patients:

Selection of Patients was done based on their iron deficiency anemia form outpatient department (OPD) of P. D. Patel Ayurvedic Hospital, teaching hospital of J. S. Ayurveda College, Nadiad, Gujarat – 387001.

Methods of collection of Data:

Patients who fulfill the criteria of diagnosis and inclusion will be included in this study irrespective of sex, caste and religion.

Inclusion criteria:

- Patients with classical features of Iron deficiency anemia
- Patients of either sex of age group 18-60 years.
- Patients with Hb% within the range of 7-11 gm/dl

Exclusion criteria:

- Patients with chronic illness

- Patients with history of all types of diabetes mellitus and hypertension.
- Patients with history of congenital disorders related with haemopoetic system
- Patients suffering from disorder associated with gastro intestinal bleeding
- Pregnant women.

Parameters of Study:

Subjective Parameters: Weakness, fatigue, palpitation, Effort intolerance, Breathlessness, and swollen feet

Objective parameters: Hb%, PCV, MCV, RBC, etc

Assessment criteria:

Patients were assessed based on their clinical history and their physical observation of the body as per the performa. All the parameters were recorded properly in performa and the result of the study was measured on the foundation of development in signs and symptoms of the diseases.

1. Changes in subjective parameters.
 2. Changes in objective parameters which are recorded in the following pattern.
- Marked relief – above 75% improvement
 - Moderate relief – 25-75% improvement

- No relief – below 25% improvement

Explanation of grades:

The grades and grade points were given to the different clinical parameters and laboratory findings for the determination of statistical assessment of results.

Grade Features

- | | | |
|---|-------------------|---------------------------------|
| 0 | No symptoms/ | No observable clinical features |
| 1 | Mild symptoms | |
| 2 | Moderate symptoms | |
| 3 | Severe symptoms | |

Adverse reaction:

Patients finding any adverse effect of drug after treatment were recorded and analyzed as per the performa.

Analysis of data:

All the observation of patients were recorded and documented properly in Case Report Form. They were analyzed by using statistical methods like student's t-test, p-test, standard deviation etc to establish the efficacy.

SELECTION OF DRUG

Ayurvedic classical text recommended the use of *Navayasa Lauha* in treatment of *Pandu roga* in a form of churna. *Navayasa Lauha* is a herbo mineral formulation and

was modified in a tablet form to overcome the disadvantage of churna and easy administration of drug to the patients. It is taken along with water or milk. Patients are given advice to take more intake of vitamin C for better absorption of iron in the blood. Thus *Navayasa Lauha* tablets were taken as a trial drug for treatment of Iron deficiency anemia or *Pandu roga*.

PROCUREMENT OF DRUG:

Vasu Helthcare, Vadodara has provided raw material for formulation of *Navayasa Lauha* tablet as a gratis samples. Direct compression method was used for formulation of *Navayasa Lauha*.

DRUG INFORMATION

Navayasa Lauha Tablet:

Navayasa Lauha is a classical herbo-mineral formulation containing 9 parts of herbs and 1 part of lauha bhasma. It is a member of lauha kalpa and mainly used for *Pandu roga* and It has reddish brown color, pungent odor, spicy and pungent taste. It is originally powdered preparation (AFI, Part-I, 7:17).

Composites of formulation:

Each tablet of *Navayasa Lauha* contains 1 part of Sunthi, Marica, Pipalli, Haritaki, Bibhitaki, Amalaki, Musta, Vidang, Chitrak and nine parts of lauha bhasma.

STUDY DESIGN

Sample size:

Minimum of 100 patients diagnosed as iron deficiency anemia will be selected for the study. Patients with HB% within the range of 7-11 gm/dl of Pandu will be administered with *Navayasa Loha* tablets (2 tablets – 250mg) twice daily, with a glass of water or milk, at morning and evening time for 1 month.

Follow up:

Patient will be reviewed at an interval of 15 days throughout the progression of study.

Duration of Study: 1 month

WITHDRAWAL OR TERMINATION OF STUDY

It is a right of a Subject to remove him at any stage of the study for any reason. Along with this, there is a right to study investigator to take out any subjects from their ongoing study due to any specific diseases, side effects, failure of treatment, protocol violations, administrative reasons or any other reasons.

ETHICS/PROTECTION OF HUMAN SUBJECTS

Informed Consent:

The subject was well educated by study designated personnel or the principal investigator about the overall study, purpose

of study, procedure to be followed during the course of study, product to be investigated , possible threats and rights of the study subjects. This can be done by the language known by subject or oral demonstration of the study was done in front of subject.

Informed consent form (ICF) will be filled by subject after complete understanding of it and dully signed by subject and principle investigator before starting up the project. Original copy of ICF will be preserved in trial master file for future use and photocopy of the ICF was given to the subject.

Independent Ethics Committees/Institutional Review Board:

Protocol and corresponding Informed Consent Form (ICF) will be revised by the Independent Ethics Committee (IEC). After the approval of protocol and ICF by IEC, subject was registered into the study.

RESULTS AND DISCUSSION

Pandu roga – iron deficiency anemia is a most prevalence disease worldwide. *Pandu roga* affects infants, pregnant and lactating women, adolescence girls and elderly people due to low intake of hemoglobin in blood.

Navayasa Lauha is a classical herbo-mineral formulation contains lauha bhasma

as a source of iron. It is used in *Pandu roga*. Clinical study of *Navayasa Lauha* was performed with iron deficiency anemic patient to check the hematinic activity of *Navayasa Lauha*.

Total 112 patients were diagnosed as iron deficiency anemia with HB% within the range of 7-11 gm/dl and were selected for the study and administered with *Navayasa loha* tablets (2 tablets – 250mg) twice daily, with a glass of water or milk, at morning and evening time for 1 month. Patients were reviewed at an interval of 15 days during the course of study for 1 month.

Fig 1 Overall results of *Navayasa luaha* in objective parameters

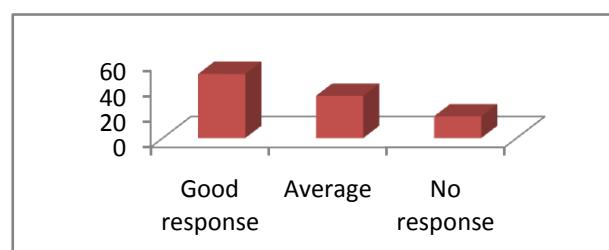


Table 1 Distribution of patients as per their Age

Age (yrs)	Male	Women	Total	Percentage
18 -20	1	15	16	16
21-30	8	22	30	29
31-40	7	12	19	18
41-50	9	14	23	22
51-60	5	10	15	15
Total	30	73	103	100

Table 2 assessment of results in overall Objective Parameters

Results	No. of patients	Percentage	Patients	Percentage
Good response - above 75% improvement	52	50	answer was observed in 50%	
Average – 25-75% improvement	34	33 ³³	of patients, average answer was observed in	
No response – below 25 % improvement	17	17	33% of patients, and no answer was observed in 17% of patients.	

Changes in clinical signs and symptoms of *Pandu roga* / Iron deficiency anemia were recorded based on calculating Hemoglobin percentage, mean cell volume, packed cell volume, random distribution red cell width and peripheral blood smear.

Out of 112 patients, 104 patients have successfully completed the study whereas remaining 8 patients did not come for follow up study and opt for discontinuation of medicine without any prior notice. Table 1 shows the distribution of patients as per theirage. As per information obtained from Table -1, incidence of disease was more common in women (71%) than men (29%). Out of 103 patients, prevalence of disease was more common in age group of 21-30 (29%) and less in age group of 51-60 (15%). It can be seen from Table 2 that out of 103

Fig 1 shows the overall effect of Navayasa luaha tablets in the objective parameters of Iron deficiency anemia patients and table 3 gives statistical analysis of overall objective parameters.

It can be concluded from the Table 3 that before treatment 97% of patients were feeling weakness which was reduced to 73% after treatment. Similarly 72% fatigue, 40% palpitation, 45% effort intolerance, 20% breathlessness and 10% swollen feet was reduced to 50%, 26%, 36%, 10% and 0%, respectively.

Table 4 and Table 5 show the statistical analysis of objective parameters at 15 days. Hb, PCV, MCV and RBC were measured at 15 days. Statistical analysis was done on based on standard deviation, t-value and p-value.

Table 3 Assessment of 103 patients based on symptoms observed

Symptoms	No. of Patients (BT)	Percentage	No of Patients (AT)	Percentage
Weakness	100	97	75	73
Fatigue	72	70	52	50
Palpitation	40	39	27	26
Effort intolerance	45	44	40	39
Breathlessness	20	19	10	10
Swollen feet	10	10	0	0

The mean difference on relief of overall parameters when compared with student T-test before and after treatment was found

highly significant ($P < 0.001$). All the results show highly significant except mean cell value data.

Table 4 Assessment of results based on Objective parameters at 15 days

Parameters	Mean	SD	SEM	t-value	p-value	Statistical Significance
Hb (BT)	10.167	0.721	0.072	16.9079	< 0.001	Highly significant
Hb (AT)	10.792	0.632	0.063			
PCV(BT)	41.360	4.808	0.480	7.6351	< 0.001	Highly significant
PCV (AT)	41.981	4.697	0.469			
MCV(BT)	85.817	10.01	5.00	0.0362	< 0.001	Not significant
MCV (AT)	86.077	10.32	5.16			
RBC (BT)	4.5364	0.419	0.089	5.4032	< 0.001	Highly significant
RBC (AT)	4.5755	0.417	0.089			

Table 5 Assessment of results based on Objective parameters at 30 days

Parameters	Mean	SD	SEM	t-value	p-value	Statistical Significance
Hb (BT)	10.167	0.721	0.072	12.5403	<0.001	Highly significant
Hb (AT)	11.422	0.694	0.069			
PCV(BT)	41.360	4.808	0.480	15.2854	<0.001	Highly significant
PCV (AT)	43.006	4.391	0.439			
MCV (BT)	85.817	10.01	5.003	0.1074	< 0.001	Not significant
MCV (AT)	86.567	9.739	4.869			
RBC(BT)	4.5364	0.419	0.089	7.7572	< 0.001	Highly significant
RBC (AT)	4.6282	0.419	0.080			

CONCLUSION

All herbs used in preparation of *Navayasa Lauha* are stomachic and carminative and helps to improve indigestion which occurs due to consumption of iron. However, the herbs increase the bioavailability of lauha bhasma and favor its absorption which increases the hemoglobin content in blood.

Amalaki is richest source of vitamin C which reduces ferric iron to ferrous iron and is better absorbed too. It is capable of enhancing RBC production as well as boost up the immunity of the body. Hence it can be concluded that Navayasa loha tablets were effective against Iron deficiency anemia and can be a better option as

compare to allopathic medicine. However further studies are require with comparison with allopathic medicine to check the effectiveness of Navayasa loha against allopathic medicine.

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