



AN AMELIORATE COMPARATIVE CLINICAL TRIAL OF NAVAYAS LOUHA SYRUP AND NISHA LOUHA SYRUP IN THE MANAGEMENT OF PANDU ROGA WITH SPECIAL REFERENCE TO IRON DEFICIENCY ANEMIA IN CHILDREN

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ABSTRACT

Anemia is a major health problem in India. Yet, a comprehensive plan of action to combat this public health problem has been still missing. There are few existing plans for the control of Iron Deficiency Anemia regarding children and pregnant women and lactating mothers. Iron deficiency is the result of long-term negative iron balance. Iron deficiency anemia (IDA) should be regarded as a subset of iron deficiency, that is, it represents the extreme lower end of the distribution of iron deficiency. Treatment options include oral and intravenous iron therapy; however, the efficacy of oral iron is limited in certain gastrointestinal conditions, such as inflammatory bowel disease, celiac disease, and autoimmune gastritis. So that ameliorate comparative clinical trial was taken with Ayurveda formulation for the diagnosis and treatment of iron deficiency anemia (IDA) with special reference to Pandu Roga. Overall, in the study Navayas Louha was found to have 76.53% and of Nisha Louha was found to have 69.33% clinical efficacy. The study showed that trial clinical efficacy of Navayas Louha syrup is better than Nisha Louha syrup in the management of iron deficiency anemia in Indian children.

Keywords: Pandu, Navayas Louha syrup, Nisha Louha syrup, IDA, Pediatric anemia.

INTRODUCTION

The Nomenclature of Pandu Roga is based on color of the body, in which whole body become pallor Pandu Roga is seen in each age group from children to old age people. Iron Deficiency Anemia is the most common and widespread nutritional disorder in the world. As well as affecting many children and women in developing countries. Iron requirements increase during the period of active growth in childhood, especially from 6 months to 3 years. In infancy, iron deficiency is most often the result of lack of exclusive breast feeding and use of un-supplemented milk diets which contain inadequate amounts of iron¹. Milk products are very poor sources of iron and prolonged breast or bottle feeding of the infant without complementary feeds after 6 months of age frequently leads to iron deficiency unless there is iron supplementation. Iron requirements are proportionately greater in premature and underweight babies². In older children, a predominantly milk and cereal based diet and food fads can also lead to IDA. The WHO Global Database on anemia for 1993–2005, covering almost half the world's population, estimated the prevalence of anemia worldwide at 25 per cent³. Although the prevalence of anemia is estimated at 9 per cent in countries with high development, in countries with low development the prevalence is 43 per cent. In absolute numbers anemia affects 1.62 billion people globally with about 293 million children of preschool age⁴.

According to WHO drug can be defined as any substance or product that is used or intended to be used to modify or explore

physiological systems or pathological states for the benefit of the recipient in older days human beings has a very strong power of observation, so abnormal color or complexion is easily detectable than any other symptom of diseases that's why our ancestor's also observed pallor or pandu complexion and named it differently as a disease⁵. We can conclude that pandu is a historic disease known to humans Ayurvedic literature (Samhitas) disease is described in the details including Nidan Panchaka and Chikitsa. None of any acharya of Ayurveda offered the detailed description regarding pandu among children but in Kashyap Samhita (Kaumarabhritya Tantra Pradhana Granth) some information regarding with pandu in children is available. Pandu roga can be correlated with the Iron deficiency Anemia (IDA) in which the symptoms like- Shwetakashi (Pallor Eyes), Aganisadashya (loss of appetite) Shwathucha Akshikootyoha (infraorbital / periorbital oedema) Nakhwakra (Nail Deformity)⁶ and hematological parameter⁷.

After considering the above facts for mankind a comparative clinical trial was selected by using two Ayurvedic formulations Navayas Louha syrup and Nisha Louha syrup in the management of Pandu roga.

MATERIALS AND METHODS

The study was done as per the guidelines of the Helsinki Declaration and after I.E.C approval. Sixty anemic Patient of either sex age between 1-15 years was randomly selected from Kaumarabhritya O.P.D. and I.P.D. of Rani Dullaiya Smriti

Ayurved Post Graduate College and Hospital, Bhopal (M.P), India. 60 anemic patients were randomly divided into two groups. 30 patients were in group A and the rest 30 were in B group. Navayas Louha syrup was received by Group A orally and Group B received Nisha Louha syrup orally 3 months. The dose was calculated by Dilling's formula. Both group's comparative statistical analysis of before and after treatment was done in this study by using graph pad prism software version -8.

The raw drugs were collected from the local market and authenticated by Dravyaguna department and both drugs were prepared under observation of Rasa shastra department at the Rani Dullaiya Smriti Ayurved Post Graduate College. The ingredients of Navayas Louha syrup and Nisha Louha syrup are mentioned in Table 1 and Table 2.

Method of collection of DATA

Ayurveda criteria like- Shwetakashi (pallor eyes), Aganisadashya (loss of appetite) Shwathucha Akshikootyoha (infra orbital/periorbital oedema) Nakhwakrata (Nail Deformity) and related routine investigation (RBC Count, HB %, MCV, MCHC).

Inclusion criteria

- Patients more than Hb 8 gram% with associated symptoms of Anemia
- Patients of age group 1-15 years of age irrespective of caste, religion, sex, habits, occupation and socio-economic status.

Exclusion criteria

- Anemia due to malaria.
- Anemia due to systemic complications like heart disease, malignancies etc.
- Anemia due to bleeding diathesis
- Thalassemia
- Sick cell anemia
- Polycythemia
- Pancytopenia
- Blood Component Transfusion

RESULT

Age wise patient distribution

Out of total 60 patients in Group A and group B, maximum patients were in age Group 6-10 years followed by age 11-15 years. They were 41.67% and 31.67% respectively. Group wise division: They were 43.33%, 26.67% and 40%, 36.67% respectively in A and B Group. (Table 3)

Sex wise patient distribution

Out of 60 patients in Group A and Group B, 33 patients were male while 27 patients were Female. It means a total 45% were female as compared to 55% were male. Group A has 63.33% Male while 36.67% Females respectively. In Group B male were 53.33% and female were 46.67% (Table 4).

Appetite wise patient distribution

Out of total 60 Patients in Group A and Group B, the maximum patients Appetite was found in Poor i.e., 41 (68.33%). In, Group A, they were 73.33%. In, Group B they were 63.33% respectively (Table 5).

Bowel wise patient distribution

Out of total 60 Patients in Group A and Group B, maximum patients Bowel were found in Constipated (71.67%). In, Group A, they were 73.33%. In, Group B they were 70% respectively (Table 6).

Social Status wise distribution

Out of total 60 patients in Group A and Group B, maximum patients' social status were Poor i.e., 32 (53.33%) (Table 7).

Effect of Group A on Shwetakashi

An assessment of Shwetakashi in patients of Pandu Roga before and after the treatment in Group-A, showed a reduction in the mean score from 1.00 to 0.40 with 60% improvement. Analysis of this data shows statistically highly significant improvement ($P < 0.001$) (Table 8).

Effect of Group B on Shwetakashi

An assessment of Shwetakashi in patients of Pandu Roga before and after the treatment with Group-B showed a reduction in the mean score from 1.00 to 0.43 after the treatment with 57% improvement. Analysis of this data shows statistically highly significant improvement ($P < 0.001$). (Table 9).

Effect of Group A on Aganisadashya

An assessment of Aganisadashya in patients of Pandu Roga before and after the treatment in Group-A showed a reduction in the mean score from 2.00 to 0.37 with 82% improvement. Analysis of this data shows statistically highly significant improvement ($P < 0.001$) (Table 10).

Effect of Group B on Aganisadashya

An assessment of Aganisadashya in patients of Pandu Roga before and after the treatment with Group-B showed a reduction in the mean score from 2.00 to 0.40 after the treatment with 80% improvement. Analysis of this data shows statistically highly significant improvement ($P < 0.001$). (Table 11).

Effect of Group A on Shwathucha Akshikootyoha

An assessment of Shwathucha Akshikootyoha in patients of Pandu Roga before and after the treatment in Group-A showed a reduction in the mean score from 1.67 to 0.50 with 70% improvement. Analysis of this data shows statistically highly significant improvement ($P < 0.001$) (Table 12).

Effect of Group B on Shwathucha Akshikootyoha

An assessment of Shwathucha Akshikootyoha in patients of Pandu Roga before and after the treatment with Group-B showed reduction in the mean score from 1.57 to 0.57 after the treatment with 64% improvement. Analysis of this data shows statistically highly significant improvement ($P < 0.001$) (Table 13).

Effect of Group A on Nakhwakrata

An assessment of Nakhwakrata in patients of Pandu Roga before and after the treatment in Group-A showed a reduction in the mean score from 0.37 to 0.03 with 91% improvement. Analysis of this data shows statistically highly significant improvement ($P < 0.001$) (Table 14).

Table 1: Navayas Louha syrup ingredients

S. No.	Common Name	Latin Name	Parts Used	Ratio
1	Haritaki	<i>Terminalia chebula</i> Retz.	Fruit	1
2	Amalaki	<i>Emblica officinalis</i> Gaertn.	Fruit	1
3	Vibhitak	<i>Terminalia bellirica</i> (Gaertn.) (Roxb.)	Fruit	1
4	Shunthi	<i>Zingiber officinale</i> Roscoe	Rhizome	1
5	Maricha	<i>Piper nigrum</i> L.	Fruit	1
6	Pippali	<i>Piper longum</i> L.	Fruit	1
7	Vidanga	<i>Embelia ribes</i> Burm.f.	Fruit	1
8	Chitraka	<i>Plumbago zeylanica</i> L.	Root	1
9	Musta	<i>Cyperus rotundus</i> L.	Rhizome	1
10	Louha bhasma	Calcined iron	-----	9
11	Honey and water	-----	-----	As per requirement ⁸

Table 2: Nisha louha syrup ingredients

S. No.	Common Name	Latin Name	Part Used	Ratio
1	Haritaki	<i>Terminalia chebula</i> Retz.	Fruit	1
2	Vibhitak	<i>Terminalia bellirica</i> (Gaertn.) (Roxb.)	Fruit	1
3	Amalaki	<i>Emblica officinalis</i> Gaertn.	Fruit	1
4	Haridra	<i>Curcuma longa</i> L.	Rhizome	1
5	Daruharidra	<i>Berberis aristata</i> DC.	Root	1
6	Kutaki	<i>Picrorhiza kurroa</i> Royle ex Benth.	Root	1
7	Louha bhasma	Calcined iron	-----	1
8	Honey and water	-----	-----	As per requirement ⁹

Table 3: Distribution of patients based on Age

Age in years	No. of Patients and Percentage					
	Group A		Group B		Total	
01-05	9	30%	6	20%	15	25%
06-10	13	43.33%	12	40%	25	41.67%
11-15	8	26.67%	11	36.67%	19	31.67%
16-20	0	0%	1	3.33%	1	1.67%

Table 4: Distribution of patients based on Sex

Sex	No. of Patients and Percentage					
	Group A		Group B		Total	
Female	11	36.67%	16	53.33%	27	45%
Male	19	63.33%	14	46.67%	33	55%

Table 5: Distribution of patients based on Appetite

Appetite	No. of Patients and Percentage					
	Group A		Group B		Total	
Good	03	10%	05	16%	08	13.33%
Moderate	05	16.67%	06	20%	11	18.33%
Poor	22	73.33%	19	63.33%	41	68.33%

Table 6: Distribution of patients based on Bowel

Bowel	No. of Patients and Percentage					
	Group A		Group B		Total	
Regular	08	26.67%	09	30%	17	28.33%
Constipated	22	73.33%	21	70%	43	71.67%

Table 7: Distribution of patients based on social status

Social Status	No. of Patients and Percentage					
	Group A		Group B		Total	
Rich	5	16.67%	5	16.67%	10	16.67%
Moderate	9	30%	9	30%	18	30%
Poor	16	53.33%	16	53.33%	32	53.33%

Table 8: Effect of Group-A on Shwetakashi (Pallor eyes) of Pandu roga

Symptom	Mean score			N	% of relief	S.D (±)	S.E (±)	t Value	P Value	Remarks
	BT	AT	BT-AT							
Shwetakashi	1.00	0.40	0.60	30	60	0.498	0.091	6.59	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 9: Effect of Group-B on Shwetakashi (Pallor eyes) of Pandu roga

Symptom	Mean score			N	% of relief	S.D (±)	S.E (±)	t value	P value	Remarks
	BT	AT	BT-AT							
Shwetakashi	1.00	0.43	0.57	30	57	0.504	0.092	6.15	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 10: Effect of Group A on Aganisadashya (Loss of appetite) of Pandu roga

Symptom	Mean score			N	% of relief	S.D (±)	S.E (±)	t value	P value	Remarks
	BT	AT	BT-AT							
Aganisadashya	2.00	0.37	1.63	30	82	0.490	0.089	18.25	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 11: Effect of Group-B on Aganisadashya (Loss of appetite) of Pandu roga

Symptom	Mean score			N	% of relief	S.D (±)	S.E (±)	t value	P value	Remarks
	BT	AT	BT-AT							
Aganisadashya	2.00	0.40	1.60	30	80	0.498	0.091	17.58	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 12: Effect of Group A on Shwathucha Akshikootyoha (Infra orbital/ Periorbital oedema) of Pandu roga

Symptom	Mean score			N	% of relief	S.D (±)	S.E (±)	t value	P value	Remarks
	BT	AT	BT-AT							
Shwathucha Akshikootyoha	1.67	0.50	1.17	30	70	0.379	0.069	16.85	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 13: Effect of Group-B on Shwathucha Akshikootyoha (Infra orbital/ Periorbital oedema) of Pandu roga

Symptom	Mean score			N	% of relief	S.D (±)	S.E (±)	t value	P value	Remarks
	BT	AT	BT-AT							
Shwathucha Akshikootyoha	1.57	0.57	1.00	30	64	0.643	0.117	8.51	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 14: Effect of Group-A on Nakhwakrata (Nail deformity) of Pandu roga

Symptom	Mean score			N	% of relief	S.D (±)	S.E (±)	“t” value	P value	Remarks
	BT	AT	BT-AT							
Nakhwakrata	0.37	0.03	0.34	30	91	0.479	0.087	3.81	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 15: Effect of Group-B on Nakhwakrata of (Pandu roga)

Symptom	Mean score			N	% of relief	S.D (±)	S.E (±)	t value	P value	Remarks
	BT	AT	BT-AT							
Nakhwakrata	0.47	0.20	0.27	14	57	0.449	0.082	3.24	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 16: Effect of Group A on Hematological parameters

Parameters	N	BT	AT	% of relief	SD	SE	t value	P value	Remarks
Hb	30	10.11	12.67	20.22	0.707	0.129	19.86	0.001	HS
MCV	30	80.99	92.66	12.60	11.71	2.14	5.45	0.001	HS
MCH	30	24.11	28.87	16.47	4.02	0.734	5.96	0.001	HS
MCHC	30	29.74	31.14	4.49	1.28	0.234	3.71	0.001	HS
RBC Count	30	4.23	4.36	2.97	0.742	0.136	0.95	0.006	NS

BT: Before Treatment, AT: After Treatment

Table 17: Effect of Group B on Hematological parameters

Parameters	N	BT	AT	% of relief	SD	SE	t value	P Value	Remarks
Hb	30	10.24	11.51	11.03	0.604	0.110	11.51	0.001	HS
MCV	30	83.33	88.23	5.55	11.75	2.14	2.28	0.005	S
MCH	30	24.74	26.91	8.07	4.23	0.772	2.81	0.005	S
MCHC	30	29.64	30.42	2.59	1.58	0.288	2.72	0.005	S
RBC Count	30	4.18	4.56	8.41	1.37	0.250	1.53	0.06	NS

BT: Before Treatment, AT: After Treatment

Effect of Group B on Nakhwakrata

An assessment of Nakhwakrata in patients of Pandu Roga before and after the treatment with Group-B showed a reduction in the mean score from 0.47 to 0.20 after the treatment with 57% improvement. Analysis of this data shows statistically highly significant improvement (P-0.001) (Table 15).

Effect of Group A on Hematological Parameters

In the group treated with Navayas Louha syrup, Hemoglobin, MCV, MCH and MCHC were increased to a statistically highly significant level (P-0.001) whereas the increase seen in total RBC count was not significant statistically (Table 16).

Effect of Group B on Hematological Parameters

In the group treated with Nisha Louha syrup statistically highly significant (P- 0.001) improvement was obtained in hemoglobin. MCV, MCH and MCHC were statistically significant, whereas the increase seen in total RBC count was not significant statistically. (Table 17).

Assessment of the total effect of therapy

Effect of treatment in group - A		
Class	Grading	No of patients
< 24	Poor Response	0
25-49	Mild Response	0
50-74	Moderate Response	13
75-100	Marked Response	17

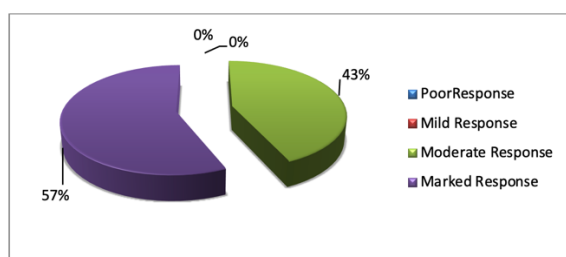


Figure 1: The overall effect of Navayas Louha syrup in Group A

Effect of Treatment in Group – B		
Class	Grading	No of patients
< 24	Poor Response	0
25-49	Mild Response	03
50-74	Moderate Response	13
75-100	Marked Response	14

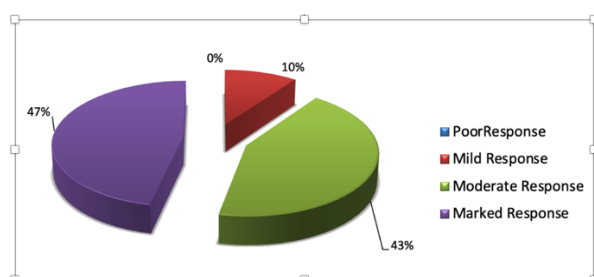


Figure 2: Effects of Nisha Louha syrup in Group B

DISCUSSION

Effect on Shwetakashi

Patients of Pandu treated with Navayas Louha syrup showed a reduction in the mean score from 1.00 to 0.40 with 60% improvement. Analysis of this data shows statistically highly significant improvement (P < 0.001). Patients of Pandu treated with Nisha Louha syrup showed reduction in the mean score from 1.00 to 0.43 after the treatment with 57% improvement. Analysis of this data shows statistically highly significant improvement (P-0.001). So, this study affirms that Navayas Louha syrup is effective in curing Shwetakashi in Pandu.

Effect on Aganisadashya

Patients of Pandu treated with Navayas Louha syrup showed a reduction in the mean score from 2.00 to 0.37 with 82% improvement. Analysis of this data shows statistically highly significant improvement (P-0.001). Patients of Pandu treated with Nisha Louha syrup showed reduction in the mean score from 2.00 to 0.40 after the treatment with 80% improvement. Analysis of this data shows statistically highly significant improvement (P-0.001). So, this study affirms that both are effective in relieving Aganisadashya in Pandu.

Effect on Shwathucha Akshikootyoha

Patients of Pandu treated with Navayas Louha syrup showed reduction in the mean score from 1.67 to 0.50 with 70% improvement. Analysis of this data shows statistically highly significant improvement (P < 0.001). Patients of Pandu treated with Nisha Louha syrup showed reduction in the mean score from 1.57 to 0.57 after the treatment with 64% improvement. Analysis of this data shows statistically highly significant improvement (P-0.001). So, this study affirms that Navayas Louha syrup is effective in curing Shwathucha Akshikootyoha in Pandu.

Effect on Nakhwakrata

Patients of Pandu treated with Navayas Louha syrup showed reduction in the mean score from 0.37 to 0.03 with 91% improvement. Analysis of this data shows statistically highly significant improvement (P < 0.001). Patients of Pandu treated with Nisha Louha syrup showed reduction in the mean score from 0.47 to 0.20 after the treatment with 57% improvement. Analysis of this data shows statistically highly significant improvement (P-0.001). So, this study affirms that Navayas Louha syrup is effective in curing Nakhwakrata in Pandu.

Effect on Hematological parameters

In the group A treated with Navayas Louha syrup, Hemoglobin, MCV, MCH and MCHC were increased to a statistically highly significant level (P-0.001) whereas the increase seen in total RBC count was not significant statistically.

In the group B treated with Nisha Louha syrup statistically highly significant (P-0.001) improvement was obtained in hemoglobin. MCV, MCH and MCHC were statistically significant, whereas the increase seen in total RBC count was not significant statistically.

A better percentage of relief was observed in the treated group in MCV, MCH and MCHC were statistically significant. Among these comparative data of Hb were highly significant statistically. On the other hand, RBC count was not statistically significant. No adverse effects (ADR) of both the trial drugs were found during the trial period. Comparative effects of both drugs on Hematological parameters are shown in Figure 3.

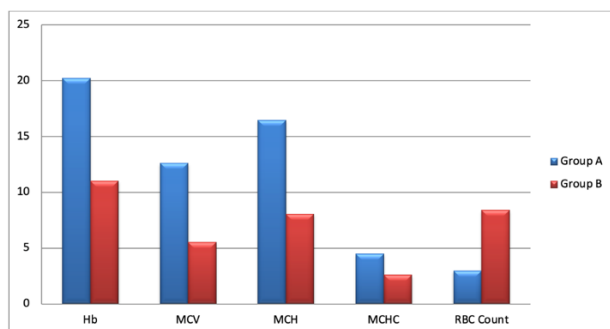


Figure 3: Comparative effects of both drugs on Hematological parameters

CONCLUSION

Both drugs (Navayas Louha and Nisha Louha) are effective in treating Pandu Roga (Iron Deficiency Anemia). Herbal ingredients present in the trial drug have antioxidant activity and may increase the bioavailability of iron. Navayas Louha is more effective in treating and maintaining HB% and MCH values. While Nisha Louha is more effective in maintaining RBC count. Herewith we conclude that the Navayas Louha have 76.53% and Nisha Louha have 69.33% clinical efficacy in the management of iron deficiency anemia in Indian children. Navayas Louha syrup showed better results in observed parameters as compared to Nisha Louha syrup.

Navayas Louha Clinical Efficacy was found to be 76.53% and Nisha Louha Clinical Efficacy was found to be 69.33% in this study.

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