



Research Article

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

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ABSTRACT

Iron deficiency is the most usual dietary deficiency worldwide, approximately 25% of the world's population suffering from iron deficiency anemia according to the World Health Organization. A Neonate has total body iron of 250 mg (80 mg/kg), obtained from maternal sources. In the first 6 months of life, during the period when the infant gets an iron-deficient milk diet, this amount decreases to 60 mg/kg. Infants fed with cow's milk are at greater risk to develop iron deficiency anemia because calcium from cow's milk is competing with iron for absorption. There are a large number of formulations (like Navayas Louha Syrup, Nisha Louha Syrup etc.) that are mentioned to prevent iron deficiency anemia in Indian children. Despite lack of scientific data regarding the clinical efficacy of Navayas Louha Syrup and Nisha Louha Syrup, an effort has been done to present the current scenario. 60 anemic patients of either sex age between 1-15 years were randomly selected from Kaumarabhritya O.P.D. and I.P.D. of Rani Dullaiya Post Graduate Ayurvedic College and Hospital, Bhopal (M.P), India. Overall, in the study Navayas Louha is 74.53% and Nisha Louha is 69.34% having clinical efficacy. The study was showed in clinical trial efficacy of Navayas Louha syrup is better than Nisha Louha syrup in the management of iron deficiency anemia in Indian children.

Keywords: Iron deficiency anemia, Pandu roga, Navayas Louha syrup, Nisha Louha syrup, Anemia in Indian children.

INTRODUCTION

The commonest nutritional deficiency disorder throughout the world is iron deficiency anemia in children. Prevalence is higher in developing countries like India. Iron deficiency anemia remains a major and global health issue that affects particularly infants, young children and women of childbearing age in developing countries. 01 gm of Hb contains 3.4 mg of iron and the daily requirement of iron in children 1 mg/day, adult male 0.9 mg/day, adult female 2.8 mg/day and in pregnancy 3.5 mg/day¹. Iron lost per day 0.5-1 mg which is independent of iron intake and 1-2 mg in menstruating woman². The common cause of iron deficiency anemia in children is in adequate dietary intake and intestinal malabsorption or the Infants³, children and adolescents may be unable to maintain normal iron balance because of the increased demands of body growth and much lower dietary intakes of iron⁴. However, this disease was identified as "Pandu Roga" in Ayurved classics and treatment mentioned thousand years ago⁵. To see the clinical efficacy of Ayurved formulation in Pandu (iron deficiency anemia) a comparative clinical trial was performed with the formulation Navayas Louha Syrup and Nisha Louha Syrup in the management of iron deficiency anemia in Indian children with special reference to Pandu roga⁶.

The raw drugs were collected from the local market and authenticated by Dravya guna department and both drugs were prepared under observation of Rasa Shastra department at the Rani Dullaiya Smriti Ayurved Post Graduate College and

Hospital. The ingredients of Navayas Louha syrup and Nisha Louha syrup are mentioned in Table 1 and Table 2.

MATERIAL AND METHODS

Sixty anemic patients of either sex age between 1-15 years were 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 rest 30 in "B" group. Navayas Louha syrup was received by Group "A" orally and Group "B" received Nisha Louha syrup orally for a period of 3 months. The dose was calculated by Dilling's formula. Both groups comparative statistical analysis of before and after treatment was done in this study by using graphpad prism software version -8. The study was carried out as per International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP) or as per Declaration of Helsinki guidelines. The informed consent was taken from the subject prior to commencement of trial.

Method of collection of data

Related investigation (RBC Count, HB %, MCV, MCHC), routine physical examination like-Nabhyaam Samantath Shoth (Paraumbilical oedema), Shwetakshi (Pallor Eyes) etc.

Inclusion criteria

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

Exclusion criteria

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

RESULT

Age wise patient distribution

Out of 60 anemic patients were divided into four age groups (Table 3). The maximum number of patient's age group was 6-10 years (41.67%) followed by age 11-15 years (31.67%).

Sex and religion wise patient distribution

Out of 60 anemic children in Group A and Group B, 33 patients were males while 27 patients were females. It means a total 45% were females as compared to 55% were males. Group A was 63.33% males while 36.67% females respectively. Group B was 46.67 % females while 53.33% males respectively. Group A and Group B maximum patients were from the Hindu religion (80%) (Table 4 and 5)

Distribution of patients based on diet

Out of total 60 patients in Group A and Group B, maximum patient's diet was Vegetarian i.e. 44 (73.33%) (Table 6)

Distribution of patients based on appetite

Out of total 60 Patients in Group A and Group B, 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 7).

Effects of Group-A on Nabhhyam Samantath Shoth

The statistical data showed Nabhhyam Samantath Shoth in patients of Pandu Roga before and after the treatment in Group-A, showed a reduction in the mean score from 2.50 to 0.63 with 75% improvement (Table 8). Analysis of this data shows statistically highly significant improvement (P- 0.001).

Effects of Group-B on Nabhhyam Samantath Shoth

The statistical data showed Nabhhyam Samantath Shoth in patients of Pandu Roga before and after the treatment with Group-B showed a reduction in the mean score from 2.60 to 0.73 after the treatment with 72% improvement (Table 9). Analysis of this data shows statistically highly significant (HS) improvement (P- 0.001).

Effect of Group A on Shwetakshi

The assessment of Shwetakshi in patients of Pandu Roga before and after the treatment in Group-A was showed reduction in the mean score from 1.00 to 0.40 with 60% improvement (Table 10). Analysis of this data shows statistically highly significant improvement (P-0.001).

Effect of Group B on Shwetakshi

An assessment of Shwetakshi in patients of Pandu Roga before and after the treatment with Group-B showed reduction in the mean score from 1.00 to 0.43 after the treatment with 57% improvement (Table 11). Analysis of this data shows statistically highly significant improvement (P-0.001).

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 (NS) statistically (Table 12).

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 (S), whereas the increase seen in total RBC count was not significant statistically (Table 13).

Table 1: Navayas Louha syrup ingredients ⁸

S. No.	Common Name	Latin Name	Parts Used	Ratio
1	Haritaki	<i>Terminalia chebula</i> Retz.	Fruit	1
2	Amalaki	<i>Emblia 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

Table 2: Nisha Louha syrup ingredients⁹

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>Emblca 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

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: Sex wise patient Distribution

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: Religion wise patient Distribution

Religion	No. of Patients and Percentage					
	Group A		Group B		Total	
Hindu	24	80%	24	80%	48	80%
Muslim	06	20%	06	20%	12	20%

Table 6: Distribution of patients based on Diet

Diet	No. of Patients and Percentage					
	Group A		Group B		Total	
Vegetarian	22	73.33%	22	73.33%	44	73.33%
Mixed	08	26.67%	08	26.67%	16	26.67%

Table 7: 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 8: Effect of Group-A on Nabhhyam Samantath Shoth (Paraumbilical Oedema in Anemia) of Pandu Roga

Symptom	Mean score			N	% of Relief	S.D (±)	S.E (±)	“t” value	P value	Remarks
	BT	AT	BT-AT							
Nabhhyam Samantath Shoth	2.50	0.63	1.87	30	75	0.776	0.142	13.17	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 9: Effect of Group-B on Nabhhyam Samantath Shoth of Pandu Roga

Symptom	Mean score			N	% of Relief	S.D (±)	S.E (±)	“t” value	P value	Remarks
	BT	AT	BT-AT							
Nabhhyam Samantath Shoth	2.60	0.73	1.87	30	72	0.628	0.115	16.26	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 10: Effect of Group-A on Shwetakshi (Pallor eyes) of Pandu Roga

Symptom	Mean score			N	% of Relief	S.D (±)	S.E (±)	“t” value	P value	Remarks
	BT	AT	BT-AT							
Shwetakshi	1.00	0.40	0.60	30	60	0.498	0.091	6.59	0.001	HS

BT: Before Treatment, AT: After Treatment

Table 11: Effect of Group-B on Shwetakshi (Pallor eyes) of (Pandu Roga)

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

BT: Before Treatment, AT: After Treatment

Table 12: Effect on Hematological parameters- Group A

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 13: Effect on Hematological Parameters- Group B

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

Table 14: Comparative Results of subjective parameters in Group-A and Group-B

BT: Before Treatment, AT: After Treatment

Parameters Signs and Symptoms	Group-A			Group-B		
	Mean score		Percentage of relief	Mean score		Percentage of relief
	BT	AT		BT	AT	
Nabhyaam Samantath Shoth (Para umbilical Oedema)	2.5	0.63	75	2.6	0.73	72
Shwetakshi (Pallor Eyes)	1	0.4	60	1	0.43	57

BT: Before Treatment, AT: After Treatment

Table 15: Comparative effect on Objective Hematological parameters in Group A and Group B

Features	Df	% of Relief		Mean difference	“t” value	P value	Remarks
		Group A	Group B				
Hb	59	20.22	11.03	9.19	6.37	0.001	HS
MCV	59	12.60	5.55	7.05	2.13	0.005	S
MCH	59	16.47	8.07	8.40	2.34	0.005	S
MCHC	59	4.49	2.59	1.90	1.88	0.005	S
RBC Count	59	2.97	8.41	-5.44	0.81	0.06	NS

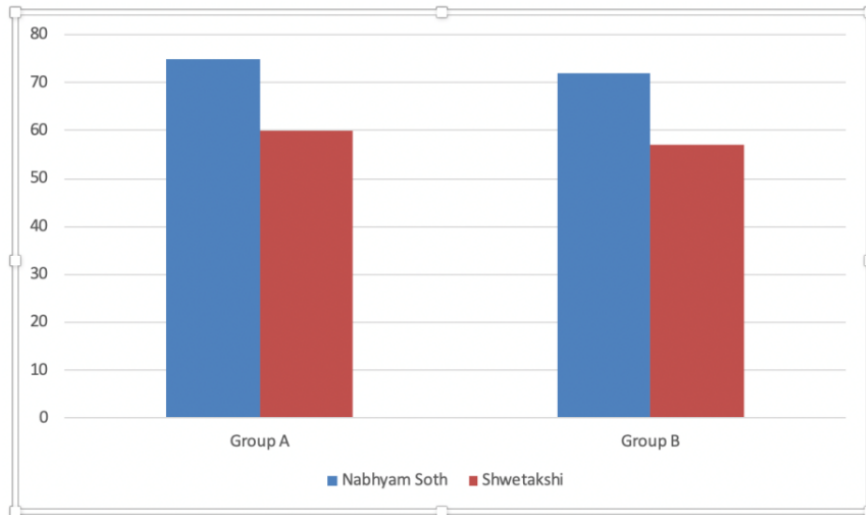


Figure 1: A comparative clinical effect of Subjective parameters of Group A & B

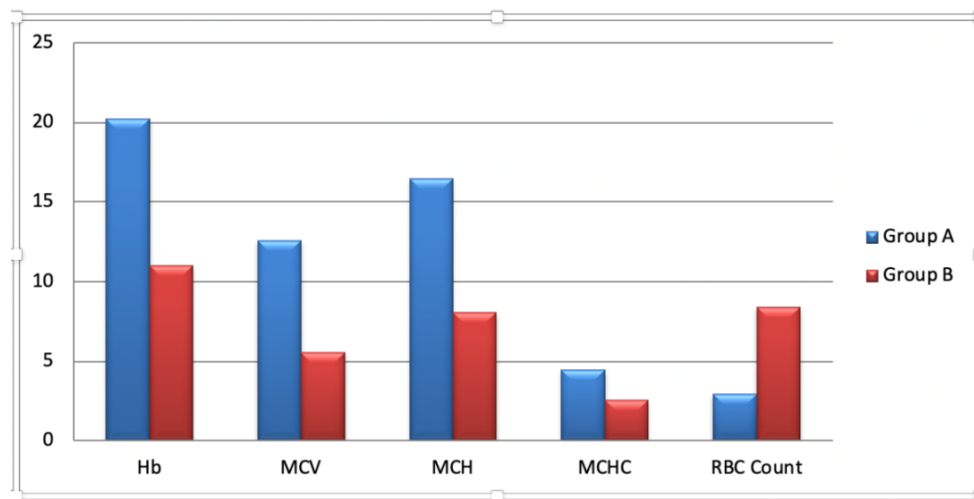


Figure 2: A comparative clinical effect of Objective parameters of Group A & B

DISCUSSION

The quint essence part of a research work is discussion. It gives plausible reasons for the observed parameter of the study. Comparative effect of treated Group A and Group B was done by applying the unpaired 't' test. The Percentage of improvement in Group A on Nabhhyam Samantath Shoth is 75%, Shwetakshi is 60% and the percentage of improvement in Group B on Nabhhyam Samantath Shoth is 72%, Shwetakshi is 57% (Table 14 and Figure 1). Better relief was observed in the Group B 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 (Table 15 and Figure 2).

CONCLUSION

Both drugs (Navayas Louha and Nisha Louha) are effective in treating Pandu Roga (iron deficiency anemia). Herbal ingredients present in the trial drug may increase the bioavailability of iron in this clinical trial. Navayas Louha is more effective in treating and in maintaining HB% and MCH values while Nisha Louha is more effective in maintaining RBC count. Here with we concluded that the Navayas Louha is 74.53% and of Nisha Louha is 69.34% have clinical efficacy in the management of iron deficiency anemia in

Indian children. Navayas Louha syrup was showed better results in the observed parameters compared to Nisha Louha syrup.

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