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Research Article

CLINICAL STUDY TO DETERMINE THE EFFICACY OF *DARVYADI LEHA* IN THE MANAGEMENT OF *PANDU ROGA* W.S.R. TO IRON DEFICIENCY ANEMIA IN CHILDREN

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ABSTRACT

The present randomized comparative clinical study was undertaken to evaluate the efficacy of *Darvyadi Leha* in the management of *Pandu Roga* w.s.r. to Iron Deficiency Anemia in children and to compare its efficacy with Iron and Folic Acid tablets. A total of 60 children aged 6–12 years with haemoglobin levels of 7–11.9g/dL fulfilling the prescribed inclusion criteria were enrolled and randomly allocated into two groups of 30 patients each. Group A received *Darvyadi Leha* at a dose of 15mg/kg/day with *Madhu* and *Ghrita*, while Group B received one Iron and Folic Acid tablet per day for 56 days. Assessment was performed using subjective and objective parameters during the treatment period, with follow-up on the 14th, 28th, 42nd and 56th days. The subjective parameters included *Panduta, Aruchi, Daurbalya, Hridya Spndana, Shwasa, Pindikodwesthana, Akshikutashotha* and *Shrama*, while objective parameters included haemoglobin, RBC count, PCV, MCV, MCH, MCHC, serum iron, serum ferritin, TIBC and peripheral blood smear. *Darvyadi Leha* produced improvement in all assessed subjective and objective parameters. The highest subjective relief in Group A was observed in *Aruchi* (80.00%) and *Daurbalya* (80.00%), followed by *Panduta* (78.38%), *Shrama* (78.38%), *Shwasa* (69.81%), *Hridya Spandana* (66.67%), *Akshikutashotha* (50.00%) and *Pindikodwesthana* (48.48%). The mean percentage improvement in subjective parameters was 65.88% in Group A and 68.92% in Group B, while objective improvement was 35.54% and 41.14%, respectively. Both interventions produced clinically meaningful improvement during the 56-day treatment period, with greater numerical improvement in the objective parameters in Group B.

INTRODUCTION

Iron Deficiency Anemia is an important nutritional disorder of childhood. Iron is required for haemoglobin synthesis and normal oxygen transport, and iron requirements increase during periods of rapid growth. Prolonged iron deficiency can adversely affect physical performance and child development.[1]

Anaemia continues to be a major public-health problem in India. NFHS-5 reported anemia in 67.1% of children aged 6–59 months at the national level. These data demonstrate the substantial burden of childhood anaemia in India.[2]

The Government of India has implemented the Anaemia *Mukt Bharat* strategy as a national approach for prevention, screening and management of anaemia among vulnerable groups.[3]

Iron status is assessed using a combination of haematological and biochemical parameters. Serum ferritin is an important indicator of iron stores, although its interpretation requires consideration of infection and inflammation.[4]

From the Ayurvedic perspective, the clinical picture of iron deficiency anemia may be studied in relation to *Pandu Roga*. *Pandu* is described as a disease in which abnormal alteration of normal complexion is prominent. The classical literature provides a detailed

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description of its *Nidana, Purvarupa, Rupa, Bheda, Samprapti* and *Chikitsa*.[5]

Darvyadi Leha was selected for the present study because it is described as a formulation indicated for *Pandu Roga*. The formulation contains *Daruharidra, Haritaki, Vibhitaki, Amalaki, Shunthi, Maricha, Pippali, Vidanga and Lauha/Ayoraja*.[6]

Previous clinical research has also demonstrated that Ayurvedic herbomineral formulations can produce improvement in clinical and haematological parameters in children with *Pandu Roga* w.s.r. to iron deficiency anemia.[7]

The present study was therefore undertaken to evaluate and compare the efficacy of *Darvyadi Leha* and iron and folic acid tablets in children suffering from *Pandu Roga* w.s.r. to iron deficiency anemia.

AIM

To evaluate and compare the efficacy of *Darvyadi leha* and iron folic acid tablet in the management of *Pandu Roga* w.s.r. to iron deficiency anemia in children.

OBJECTIVES

Primary objective

To evaluate and compare the efficacy of *Darvyadi leha* and iron folic acid tablet in the management of *Pandu Roga* w.s.r. iron deficiency anemia in children

Secondary Objective

1. To evaluate and compare the efficacy of *Darvyadi Leha* and Iron folic acid tablet in the management of *Pandu Roga* w.s.r. to iron deficiency anemia in children as per subjective criteria.
2. To evaluate and compare the efficacy of *Darvyadi leha* and iron folic acid tablet in the management of *Pandu Roga* W.s.r. to iron deficiency anemia in children as per objective criteria (hemoglobin, MCV, MCH, MCHC, PBS, serum ferritin, serum iron, TIBC, urine routine and microscopic (if needed), stool routine and microscopic (if needed)

MATERIAL AND METHOD

Study Design- Randomized comparative controlled clinical study.

Study Setting

The study was conducted through the Government Ayurveda Hospital, Moti Chohatta, Udaipur, School Health Check-up Camps and the OPD of the Postgraduate Department of *Kaumarbhritya/ Balroga*, M.M.M. Government Ayurvedic College, Udaipur.

Sample Size - 60 children

Age - 6–12 years

Group Distribution

Group	Patients	Intervention	Dose	Duration	*Anupana*
A	30	*Darvyadi Leha*	15 mg/kg/day	56 days	*Madhu + Ghrita*
B	30	Iron + Folic Acid tablet	1 tablet/day	56 days	Water

Inclusion Criteria

- Children aged 6–12 years
- Either sex
- Hb 7–11.9 g/dL
- Parents/guardians willing to provide consent.
- Clinical features suggestive of *Pandu Roga* w.s.r. to iron deficiency anemia.

Exclusion Criteria

- Children below 6 years or above 12 years.
- Hb below 7g/d
- Major systemic illness requiring long-term treatment, malignancy, tuberculosis, UTI, bleeding disorders, hypersensitivity to trial drug or participation in another clinical trial were excluded.

Assessment Criteria

For assessment of the efficacy of the trial therapy, following parameters will be adopted.

Subjective Criteria: Based on clinical features of Anemia according to both modern and Ayurvedic parameters are discussed below.

Special scoring pattern will be adopted for the symptom.

***Aruchi* (loss of appetite)**

S.No.	*Aruchi* (loss of appetite)	Condition	Score
1.	Very good appetite	None	0
2	Irregular	Irregular	1
3	Occasionally poor appetite	Moderate	2
4	Frequently persistent very poor appetite	Severe	3

***Panduta* (Pallor)**

S.No.	*Panduta* (Pallor)	Condition	Score
1	No pallor	None	0
2	Pallor of conjunctiva	Mild	1
3	Pallor of conjunctiva, nails tongue	Moderate	2
4	Pallor of conjunctiva, nails, tongue, skin, palm and soles	Severe	3

***Daurbalya* (weakness)**

S.No.	*Daurbalya* (weakness)	Condition	Score
1	No	None	0
2	Occasionally in normal activity	Mild	1
3	Persistent in normal activity	Moderate	2
4	Occasionally in heavy activity	Severe	3

***Hridya Spandanam* (Palpitation)**

S.No.	*Hridya Spandanam* (Palpitation)	Condition	Score
1	No palpitation on usual activity	None	0
2	Ocassionally on heavy exertion	Mild	1
3	On light exertion	Moderate	2
4	During rest	Severe	3

***Shwasa* (dyspnea)**

S.No.	*Shwasa* (dyspnea)	Condition	Score
1	No	None	0
2	Occasionally on exertion	Mild	1
3	Walking upstairs/quick moving	Moderate	2
4	On bed	Severe	3

***Pindikodwesthana* (Leg cramps)**

S.No.	*Pindikodwesthana* (Leg cramps)	Condition	Score
1	No	None	0
2	Mild leg cramp only at night	Mild	1
3	Leg cramps present in night or exertion	Moderate	2
4	Leg cramp present throughout the day	Severe	3

***Akshikutashotha* (Periorbital oedema)**

S.No.	*Akshikutashotha* (Periorbital oedema)	Condition	Score
1	No	None	0
2	Periorbital oedema in morning for 1 hour	Mild	1
3	Periorbital oedema in morning for 2 hours	Moderate	2
4	Periorbital oedema in morning for 6 hours	Severe	3

***Shrama* (Fatigue)**

S.No.	*Shrama* (Fatigue)	Condition	Score
1	No	None	0
2	Occasionally in normal activity	Mild	1

3	Persistent in normal activity	Moderate	2
4	Occasionally in heavy activity	Severe	3

Objective Criteria

- CBC (Hb%, RDW, RBC count, MCV, MCH, MCHC), PBS, serum ferritin, serum iron, TIBC, urine routine and microscopic (if needed), stool routine and microscopic (if needed).
- Reference range of hemoglobin will be used as per WHO classification:

Table 1: WHO classification of HB (gm/dl)

Severity	Hemoglobin (gm/dl)
Mild	10-11.9gm/dL
Moderate	7-9.9gm/dL
Severe	Below 7gm/dL

Follow Up- 14th day → 28th day → 42nd day → 56th day

The trial duration was 56 days and all 60 enrolled children completed the study without drop-out.

Observations of Subjective Criteria

Characteristic	Sub group	N. (%)
Age group	6–7 years	15 (25.00%)
	8–9 years	17 (28.33%)
	10–11 years	16 (26.67%)
	11–12 years	12 (20.00%)
Sex	Male	14 (23.33%)
	Female	46 (76.67%)
Religion	Hindu	51 (85%)
	Muslim	7(11.67%)
	Jain	2 (3.33%)
Socioeconomic Status	Upper class	0 (0%)
	Upper middle class	5 (8.33%)
	Lower middle class	19 (31.67%)
	Upper lower class	29 (48.33%)
	Lower class	7 (11.67%)
Habitat	Rural	35 (58.33%)
	Urban	25 (41.67%)
Diet	Vegetarian	43 (71.67%)
	Mixed	17 (28.33%)
	Non-vegetarian	0
Agni	*Samagni*	0
	Vishamagni	21 (35.00%)
	Tikshnagni	5 (8.33%)
	Mandagni	34 (56.67%)
Koshtha	*Krura*	11 (18.33%)
	Madhyama	31 (51.67%)
	Mridu	18 (30.00%)
Jihwa	*Sama*	45 (75.00%)

	Nirama	15 (25.00%)
Nidra	*Prakruta Nidra*	21 (35.00%)
	Alpanidra	17 (28.33%)
	Atinidra	22 (36.67%)
Prakriti	*Vatapittaja Prakriti*	25 (41.67%)
	Pittakaphaja Prakriti	19 (31.67%)
	Vatakaphaja Prakriti	16 (26.67%)
Samhanana	*Pravara*	5 (8.33%)
	Madhyama	37 (61.67%)
	Avara	18 (30.00%)
Satmya	*Ekarasa*	*9 (15.00%)*
	Sarvarasa	*13 (21.67%)*
	Vyamishra	*38 (63.33%)*
Vyayama Shakti	*Pravara*	*5 (8.33%)*
	Madhyama	*27 (45.00%)*
	Avara	*28 (46.67%)*
	Pravara	7 (11.67%)
	Madhyama	25 (41.67%)
	Avara	28 (46.67%)
Abhyvarana Shakti	*Pravara*	7 (11.67%)
	Madhyama	27 (45.00%)
	Avara	26 (43.33%)
Severity of anaemia	Mild (Hb 10 – 11.9 gm/dL)	14 (23.33%)
	Moderate (Hb 7 – 9.9 gm/dL)	46 (76.67%)
	Severe (Hb < 7 gm/dL)	0
Baseline severity of *Aruchi*	Absent (0)	0 (0%)
	Mild (1)	11 (18.3%)
	Moderate (2)	49 (81.7)
	Severe (3)	0 (0%)

Table 2: Baseline severity of *Panduta* (pallor) in 60 patients of *Pandu Roga*

Grade	Total	
	N	%
Absent (0)	0	0
Mild (1)	51	85
Moderate (2)	9	15
Severe (3)	0	0
Total	60	100

The above table presents that in the present study, the maximum number of patients i.e. 51 (85.0%) had Mild (1), followed by 9 (15.0%) Moderate (2).

Table 3: Baseline severity of *Daurbalya* (weakness) in 60 patients of *Pandu Roga*

Grade	Total	
	N	%
Absent (0)	3	5
Mild (1)	16	26.7
Moderate (2)	39	65
Severe (3)	2	3.3
Total	60	100

The above table presents that in the present study, the maximum number of patients i.e. 39 (65.0%) had Moderate (2), followed by 16 (26.7%) Mild (1), 3 (5.0%) Absent (0).

Table 4: Baseline severity of *Hridya Spandana* (palpitation) in 60 patients of *Pandu Roga*

Grade	Total	
	N	%
Absent (0)	14	23.3
Mild (1)	25	41.7
Moderate (2)	21	35
Severe (3)	0	0
Total	60	100

The above table presents that in the present study, the maximum number of patients i.e. 25 (41.7%) had Mild (1), followed by 21 (35.0%) Moderate (2), 14 (23.3%) Absent (0).

Table 5: Baseline severity of *Shwasa* (dyspnea) in 60 patients of *Pandu Roga*

Grade	Total	
	N	%
Absent (0)	38	63.3
Mild (1)	18	30
Moderate (2)	4	6.7
Severe (3)	0	0
Total	60	100

The above table presents that in the present study, the maximum number of patients i.e. 38 (63.3%) had Absent (0), followed by 18 (30.0%) Mild (1), 4 (6.7%) Moderate (2).

Table 6: Baseline severity of *Pindikodweshtana* (leg cramps) in 60 patients of *Pandu Roga*

Grade	Total	
	N	%
Absent (0)	19	31.7
Mild (1)	25	41.7
Moderate (2)	16	26.7
Severe (3)	0	0
Total	60	100

The above table presents that in the present study, the maximum number of patients i.e. 25 (41.7%) had Mild (1), followed by 19 (31.7%) Absent (0), 16 (26.7%) Moderate (2).

Table 7: Baseline severity of *Akshikutashotha* (periorbital oedema) in 60 patients of *Pandu Roga*

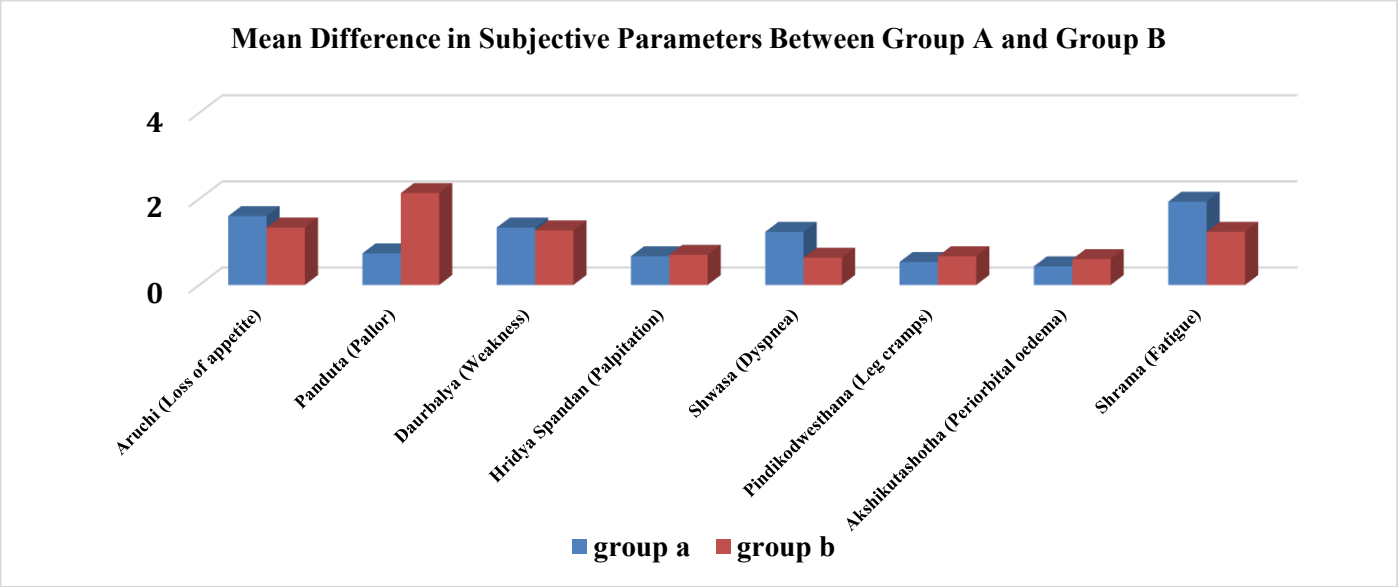
Grade	Total	
	N	%
Absent (0)	44	73.3
Mild (1)	14	23.3
Moderate (2)	2	3.3
Severe (3)	0	0
Total	60	100

The above table presents that in the present study, the maximum number of patients i.e. 44 (73.3%) had Absent (0), followed by 14 (23.3%) Mild (1), 2 (3.3%) Moderate (2).

RESULT

Inter-group comparison of the effect of therapy on subjective parameters using the Mann–Whitney U test

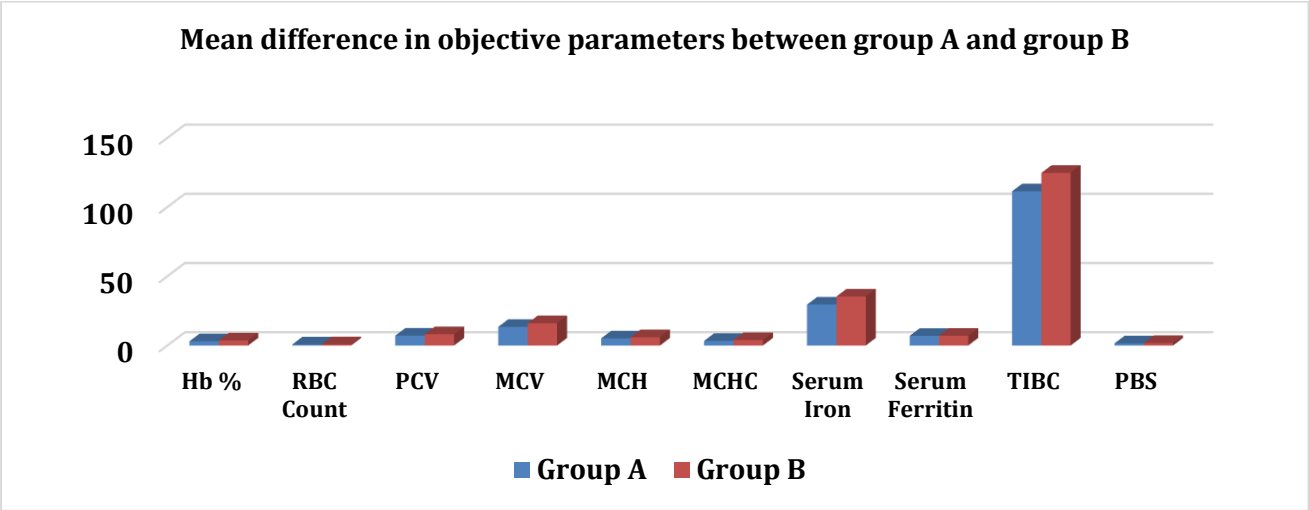
S.No.	Symptoms	Group	Dif. of mean	SD ±	SE ±	U value	P value	Significance
1	*Aruchi* (loss of appetite)	A	1.600	0.89	0.16	460.0	0.8840	NS
		B	1.333	1.15	0.21			
2	*Panduta* (pallor)	A	1.933	0.91	0.17	395.0	0.3922	NS
		B	2.133	0.90	0.16			
3	*Daurbalya* (weakness)	A	1.600	0.89	0.16	543.0	0.1465	NS
		B	1.267	0.83	0.15			
4	*Hridya Spandan* (palpitation)	A	0.667	0.92	0.17	420.5	0.6367	NS
		B	0.700	0.79	0.15			
5	Shwasa (dyspnea)	A	1.233	1.01	0.18	474.0	0.7044	NS
		B	0.633	0.67	0.12			
6	*Pindikodwesthana* (leg cramps)	A	0.533	0.90	0.16	378.0	0.2332	NS
		B	0.667	0.76	0.14			
7	*Akshikutashotha* (periorbital oedema)	A	0.433	0.63	0.11	380.0	0.2438	NS
		B	0.600	0.62	0.11			
8	*Shrama* (fatigue)	A	1.933	0.91	0.17	441.5	0.9003	NS
		B	1.233	0.82	0.15			



Graph 5: Mean Difference in Subjective Parameters Between Group A and Group B

Inter-group comparison of the effect of therapy on objective parameters using the Unpaired Student's t-test

S.No.	Investigation	Group	Diff. of mean	SD ±	SE ±	t value	P value	Significance
1	Hb %	A	3.04	0.53	0.10	4.67	<0.0001	HS
		B	3.65	0.48	0.09			
2	RBC Count	A	0.79	0.16	0.03	2.85	0.0060	S
		B	0.91	0.17	0.03			
3	PCV	A	7.14	1.38	0.25	2.93	0.0049	S
		B	8.17	1.36	0.25			
4	MCV	A	13.45	2.89	0.53	3.37	0.0013	S
		B	16.11	3.21	0.59			
5	MCH	A	5.14	0.71	0.13	4.36	<0.0001	HS
		B	5.97	0.77	0.14			
6	MCHC	A	3.32	0.97	0.18	2.10	0.0402	S
		B	3.91	1.21	0.22			
7	Serum Iron	A	29.57	5.04	0.92	3.48	0.00097	HS
		B	35.40	7.69	1.40			
8	Serum Ferritin	A	6.98	3.00	0.55	2.28	0.0263	S
		B	7.07	4.06	0.74			
9	TIBC	A	111.40	11.37	2.08	4.30	<0.0001	HS
		B	124.73	12.60	2.30			
10	PBS	A	1.53	0.78	0.14	1.24	0.2201	NS
		B	1.80	0.89	0.16			

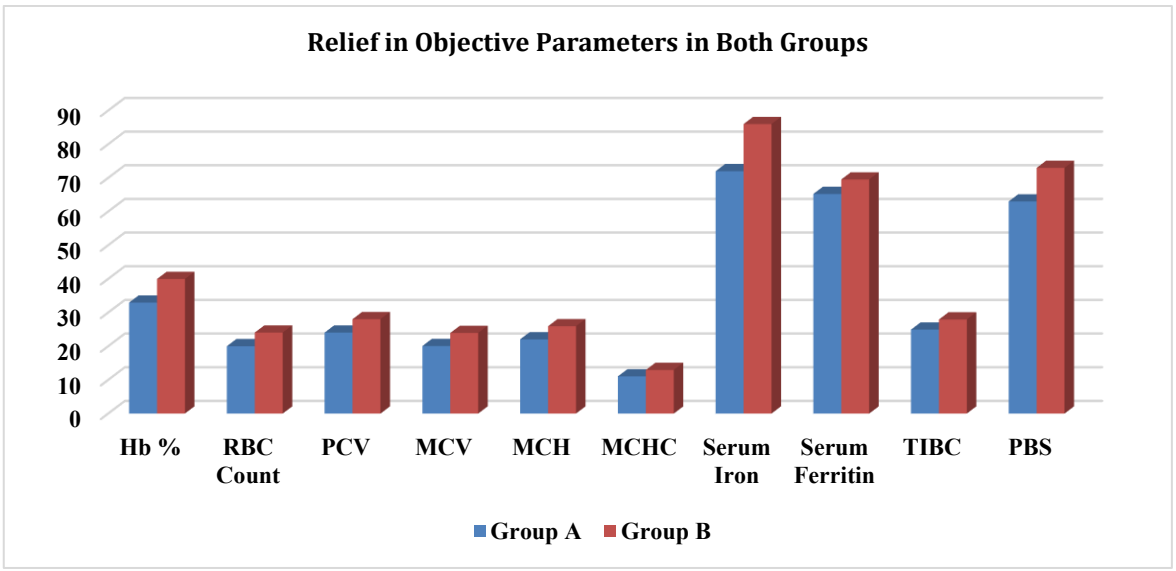


Graph 6: Mean Difference in Objective Parameters Between Group A and Group B

Subjective Parameters – Percentage of Relief

S.No.	Subjective Parameter	Group A	Group B	Total
1	*Aruchi*	80.00%	72.73%	70.85%
2	*Panduta*	78.38%	84.21%	81.29%
3	*Daurbalya*	80.00%	71.70%	75.85%
4	*Hridya Spandana*	66.67%	67.74%	67.20%
5	*Shwasa*	69.81%	61.29%	63.00%
6	*Pindikodwesthana*	48.48%	64.52%	56.50%
7	*Akshikutashotha*	50.00%	64.29%	57.14%
8	*Shrama*	78.38%	64.91%	67.36%
	Average percentage	65.88%	68.92%	67.40%

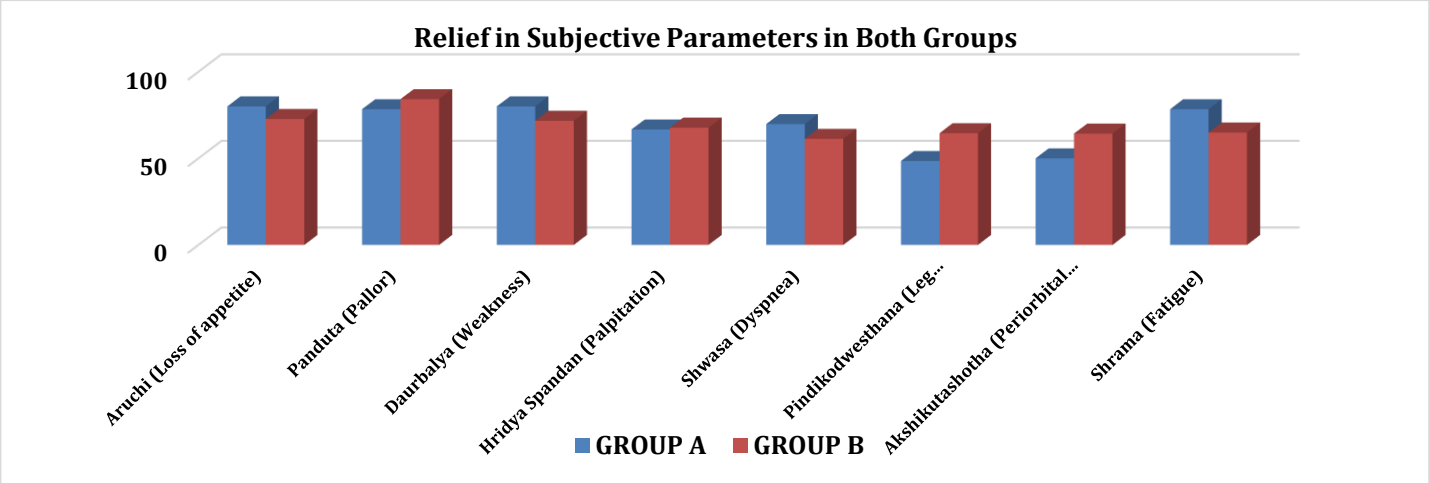
These values are taken from the study's final comparative results table.



Graph 7: Relief in objective parameters in both groups

Objective Parameters – Percentage of Relief

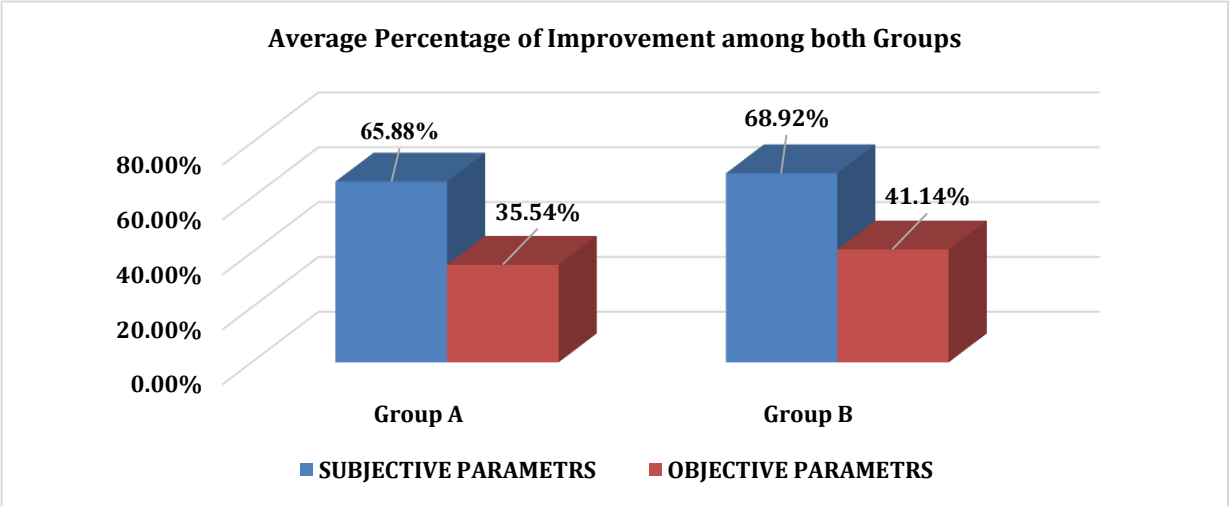
S.No	Objective Parameter	Group A	Group B	Total
1	Hb %	32.97%	39.97%	36.47%
2	RBC Count	20.01%	24.05%	22.03%
3	PCV	24.05%	28.05%	26.05%
4	MCV	20.05%	23.95%	22.00%
5	MCH	22.04%	25.95%	24.00%
6	MCHC	11.04%	12.95%	12.00%
7	Serum Iron	72.00%	85.99%	78.99%
8	Serum Ferritin	65.23%	69.52%	67.28%
9	TIBC	24.95%	27.95%	26.45%
10	PBS	63.01%	72.97%	67.99%
	Average percentage	35.54%	41.14%	38.34%



Graph 8: Relief in Subjective Parameters in Both Groups

Overall Improvement

Parameter category	Group A – *Darvyadi Leha*	Group B – Iron + Folic Acid
Subjective parameters	65.88%	68.92%
Objective parameters	35.54%	41.14%



Graph 9: Average Percentage of Improvement among both Group

The study data therefore show meaningful improvement in both groups, with greater numerical improvement in Group B in the overall objective parameters.

DISCUSSION

The present study included 60 children aged 6–12 years, with 30 children in each treatment group. All 60 children completed the 56-day treatment period, with no reported drop-out.

Among the subjective parameters, *Aruchi* and *Daurbalya* showed the highest relief in Group A (80.00% each). This indicates substantial improvement in appetite and weakness during treatment.

Panduta showed 78.38% relief, which is particularly relevant because alteration of normal complexion is the cardinal clinical feature around which the classical concept of *Pandu Roga* is described. *Shrama* showed 78.38% relief, while *Shwasa* showed 69.81% relief. *Hridya Spandana* showed 66.67% relief. *Akshikutashotha* and *Pindikodwesthana* showed 50.00% and 48.48% relief, respectively.

The average percentage of improvement in subjective parameters was 65.88% in Group A and 68.92% in Group B. Thus, both interventions produced substantial improvement in the clinical manifestations of *Pandu Roga*.

In objective parameters, the highest improvement in Group A was observed in Serum Iron (72.00%), followed by serum ferritin (65.23%) and PBS (63.01%). The average objective improvement was 35.54% in Group A compared with 41.14% in Group B.

None of the eight subjective parameters showed a statistically significant difference between the two groups (P>0.05). *Aruchi* (U=460.0, P=0.8840), *Panduta* (U=395.0, P=0.3922), *Daurbalya* (U=543.0, P=0.1465) and *Shrama* (U=441.5, P=0.9003) were all statistically comparable, as were *Hridya Spandan, Shwasa, Pindikodwesthana and Akshikutashotha*.

This indicates that the symptomatic relief afforded by *Darvyadi Leha* was statistically indistinguishable from that produced by standard oral iron and folic acid therapy.

Highly significant differences favouring Group B were observed in Hb % (t=4.669, P<0.0001), MCH (t=4.358, P<0.0001), serum iron (t=3.477, P=0.00097), TIBC (t=4.303, P<0.0001). Statistically significant differences, also favouring Group B, were recorded in RBC Count (t=2.854, P=0.0060), PCV (t=2.927, P=0.0049), MCV (t=3.368, P=0.0013), MCHC (t=2.098, P=0.0402), serum ferritin (t=2.280, P=0.0263).

The findings indicate that *Darvyadi Leha* produced substantial improvement in both clinical and laboratory parameters. However, the numerical objective response was greater in the iron and folic acid group.

The findings are consistent with the broader clinical literature in which Ayurvedic iron-containing formulations have shown improvement in haemoglobin and other haematological parameters in *Pandu Roga*/IDA. The present study should nevertheless be interpreted on the basis of its own data rather than by assuming equivalence with other formulations.

CONCLUSION

The present clinical study demonstrated that *Darvyadi Leha* produced meaningful improvement in children suffering from *Pandu Roga* w.s.r. to iron deficiency anemia.

The maximum subjective relief in Group A was observed in *Aruchi* (80.00%) and *Daurbalya* (80.00%), followed by *Panduta* (78.38%), *Shrama* (78.38%), *Shwasa* (69.81%), *Hridya Spandana* (66.67%), *Akshikutashotha* (50.00%) and *Pindikodwesthana* (48.48%).

The mean subjective improvement was 65.88% with *Darvyadi Leha* and 68.92% with iron and folic acid, while the mean objective improvement was 35.54% and 41.14%, respectively.

Therefore, both interventions were clinically beneficial, while iron and folic acid demonstrated greater numerical improvement in the objective haematological parameters during the 56-day study period.

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