Original Research Paper

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Ayurveda

A RANDOMIZED CONTROLLED CLINICAL TRIAL ON DARVYADI LEHA IN PANDU ROGA (IDA) IN CHILDREN.

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ABSTRACT **Aim:** Evaluation of efficacy of the compound Darvyadi Leha Avleha in children with IDA. **Study Design:** Open label, Randomized, Standard controlled **Material and Methods:** The study was conducted on 40 children of IDA for a period of three months. Clinical presentation and haematological parameters were documented before and after the completion of treatment. **Statistical Analysis Used:** Observations of the study were analysed and findings were evaluated by using Statistical technique was adopted for data viz.: - Wilcoxon Signed Rank test, Mann Whitney U-test, Paired t-test and Unpaired t- test. SPSS software was used. **Results:** Observations recorded in the clinical trials were assessed and the result obtained was analysed statistically. Overall assessment of both drugs was done for subjective and objective parameters based on the significance of statistical test. Marked improvement was observed in 15% of patients in group-A and 35% in group- B. Complete relief was observed in 5% patients of group A and 35% patients of group B. Moderate improvement was observed in 50% patients of group A and 25% patients of group B. Mild improvement was observed in 30% patients in group A 5% in group B. **Conclusion:** It is concluded from the result that there is significant effect of Darvyadi Leha on sign and symptoms of Pandu Roga comparable to that of iron syrup with no side effects.

KEYWORDS : Increase hemoglobin by *Ayurveda,* iron deficiency, *Pandu Roga*, management of iron deficiency anemia by Ayurveda, *Darvyadi Leha*.

INTRODUCTION: -

Iron deficiency is the most common cause of nutritional anemia.[1] *Pandu Roga* can be compared with anemia effectively on the ground of its similar clinical presentation. It is a common prevalent disease in the society. Iron deficiency anemia arises when the balance of iron intake, iron stores, and the body's loss of iron are insufficient to fully support production of erythrocytes.[2] The term '*Pandu Roga*' is given due to predominance of *Pandubhava* (paleness), which can be seen all over the body.

In developing countries, it is more prevalent among infants and children[3]. Children during this phase of rapid growth such as pre-school age and adolescence are at high risk for development of IDA.[4] Global statistics indicate that approximately 25% of older children are suffering from anemia, and 30% of non-pregnant women and 42% pregnant women, and 17% of elderly people (rising to 40-50% of those admitted to hospital or living in nursing homes), demonstrating that it is a very large and important health problem.[5]

Anemia prevalence in young children continues to remain over 70% in most parts of India and Asia despite a policy being in place and a program that has been initiated for a long time. [6]

As Allopathic iron preparations have many adverse effects, the present study was carried out to study the efficacy of an Ayurvedic formulation *Darvyadi Leha* with the aim that herbo-mineral compounds may be effective to manage childhood IDA without any side effects by assessing subjective and objective parameters.

MATERIAL AND METHODS: -

Study design: -

A randomized, open- label controlled clinical study was conducted in children suffering from *Pandu Roga* IDA.

Inclusion Criteria-

- Patients between the age group of 6-12 years irrespective of gender.
- Primarily the patients were selected on the basis of the presence of classical symptomatology along with laboratory parameters of *Pandu Roga* (IDA).
- Hemoglobin<11mg/dl.
- Only iron deficiency anemia was included.

Exclusion Criteria-

- Other anemias except IDA.
- Known cases of hemoglobinopathies especially Thalassemia.
- Associated cardiac complaints.
- Hemoglobin below 7.5g/dl.
- Patients with conditions causing chronic blood loss.
- Defective absorption, sprue syndrome.
- Known cases of chronic debilitating illness like TB, Juvenile Diabetes etc.

Discontinuation Criteria-

- Patient not willing to continue.
- Appearance of any severe complication.
- Any other severe acute illness.
- Leave against medical advice

Selection of Drug

Darvyadi Leha is an *Ayurvedic* herbo-mineral formulation mentioned in Charak *Samhita* under *Pandu Roga* chapter. The compound was modified into *Avleha* form to make administration easy for children *Darvyadi Leha* suspension was taken as trial drug for the present research study. The standard drug iron syrup which was taken as control drug.

Ethical Clearance: -

Ethical clearance was obtained from Institutional Ethics Committee prior to patient's enrolment vide letter no. UAU/GC/IEC/2020/9

CTRI :-

The trial was registered in the clinical trial registry of India before commencement of patient enrolment. Registration number for the trial is CTRI/2020/04/02492.

Procurement of the Drug:-

Trial drug was prepared and manufactured from a GMP Certified *Ayurveda* pharmacy (Hans pharmacy Sidkul, Haridwar). It was prepared in *Avleha* form in order to enhance its palatability and for easy administration in children. The control drug named Ferrogril-XT, manufactured by United Laboratories (a WHO GMP compliance & ISO 9001:2015 certified company) marketed by Pharmacon, Lifesciences Pvt. Ltd. Batch no. U20H102S, Mfg. date 08-2020.

Method of Treatment /Intervention: -

Cases registered for the study were divided into 2 groups using chit box method.

Selected drugs-

1. *Darvyadi Leha* (trial drug)

2. Iron syrup (control drug)

Composition of medicine- *Darvyadi Leha (Avleha)-*
Daruharidra, Haritki, Vibhitak, Aamalki, Shunthi, Pippli, Marich,Vidang, Ayoraj.[7]

2. Iron syrup- Contains ferrous ascorbate.
Preparation medicine-
Firstly, *Yavakuta* of all the 8 ingredients (each 1kg) of *Darvyadi Leha* was done. *Kwatha* of the *Yavakuta* drugs was prepared as instructed in Shaarangadhara *Samhita*. The drugs in *Yavakuta* form were boiled with 16 times of water under low heat and reduced to 1/8th and then filtered. Two kg ghee was added to this filtrate and heated until the *Avaleha* was attained then 150 gm of *Lauh Bhasma* was added to the prepared *Avleha.* Finally, after cooling the preparation 10kg *Madhu* was added to it. In this way18 kg of *Darvyadi Leha* was obtained.

Storage of medicine- The *Avleha* was kept in good quality pet bottles.

Dose of Medicine:
1.Darvyadi Leha (Avleha)- As per ***Yog Ratnakar*** **(Yo. Ra. Ba. Ro. Chi. page 439)**

2. Iron syrup - 4mg/kg/day BD, in between meals.

Route of Administration: Oral
Procedure:
- Group A was administered with *Darvyadi Leha* which was prepared in *Avleha* form to make administration easy for children. Dose of medicine was decided as per *Yog Ratnakar.*
- Group B was administered with iron syrup. Dose- 4mg/kg/day BD orally, in between meals.

Standardization of *Darvyadi Leha-*
The drug was manufactured from a GMP Certified *Ayurveda* pharmacy (Hans pharmacy Sidkul, Haridwar). Ref no.16/HH/2020. Date-20/06/2020

(j) Primary Endpoint:
- Improvement in Hb g/dl.

(k) Secondary Endpoints
- Reduction in signs and symptoms of *Pandu Roga* (IDA) as mentioned in *Ayurvedic* classical texts.
- Improvement in the hematological parameters TLC, DLC, RBC count, hematocrit, MCV, MCH, MCHC, RDW-CV, platelet count, MPV, ESR
- **Level of Study: -**OPD / IPD level
- **Period of Study: -**2 years
- **Duration of trial: -** 3 months
- **Follow-Up:**

The assessment of the patients was done at the interval of 30 days i.e.
- At registration ®,
- First follow up (F1-at 30 days),
- Second follow up (F2-at 60days),
- Third follow up (F-3 at 90 days) and
- Fourth follow up (F4-97th day) -one week after completion of treatment.

Assessment Criteria-
The assessment of trial was done on the basis of following parameters: -
1. Subjective parameters
2. Objective parameters.

(I) Subjective parameters:
–It includes assessment of clinical features of *Pandu Roga* (IDA) as described in *Ayurveda* and modern texts: -
1. *Pandu Varna* (Pallor)
2. *Akshikootshoth* (Periorbital swelling)
3. *Pindikodweshtana* (Leg cramps)
4. *Ayasena Shwasa* (exertion dyspnoea)
5. *Daurbalya* (General weaknes
6. *Aruchi* (Loss of appetite)

- Grading and scoring system was adopted for assessing each clinical feature before the commencement of trial and after completion of trial.

(ii) Objective parameters: –
The objective assessment will be done on the basis of haematological parameters.
- Complete Blood Count (Hb% TLC, DLC, RBC count, hematocrit, MCV, MCH, MCHC, RDW-CV, platelet count, MPV)

1. Grading of blood hemoglobin level[16]
- G0—Hemoglobin level > 11g/dL
- G1—Hemoglobin level 9.5 g/dL to <11g/dL
- G2—Hemoglobin level 7.5 g/dL to <9.5g/dL

Investigations:
- Complete Blood Count (Hb% TLC, DLC, RBC count, hematocrit, MCV, MCH, MCHC, RDW-CV, platelet count, MPV)
- Urine (routine/microscopic)
- Stool examination (ova/cyst/occult blood)

ADR:
ADR reported, if any is mentioned in the discussion section.

Analysis of data and use of statistical methods
Observations documented during the study were analysed and findings were evaluated with the help of the following statistical methods to establish the efficacy by using SPSS software.

1. **Wilcoxon Signed Rank test**
2. **Mann Whitney U-test**
3. **Paired t-Test**
4. **Unpaired t-**

- **Level of Significance:**
- Not significant - (p>0.05)
- Significant - (p<0.05)
- Highly Significant - (p <0.001)
- Overall effect of therapy was calculated on the basis of percentage. The obtained result was measured according to the grades given below:

Table no. 26: Overall response of the therapy

S. No.	RESPONSE CATEGORY	IMPROVEMENT
1.	100% relief	Cured
2.	75-99% relief	Marked improvement
3.	>50-75% relief	Moderate improvement
4.	>25-50% relief	Mild improvement
5.	< 25 % relief	No improvement

Observation:-
Total 40 patients of *Pandu Roga* (IDA) had participated in this research study. All the patients had completed the trial for the period of 90 days. The patients were assessed on basis of subjective graded clinical parameters and objective lab investigations. The demographic profile of each patient and following observations were recorded in case record proforma.

Considering the inclusion and exclusion criteria the whole study is divided under following headings:
A. Demographic profile
B. Clinical profile

A. Demographic profile
In the present study maximum number of patients i.e., 67.5% belonged to the age group of 9-12 years followed by 32.5% of the patients from the age group of 6-8 years. Maximum number of patients were female children i.e., 67.5% where as 32.5% were male children. Maximum number of patients i.e., 82.5% were Hindu, followed by 17.5% Muslims. Most of the patients i.e., 52.5% patients belonged to lower class followed by 47.5% from middle class of the society. 65% patients have mix diet and 35% have vegetarian diet. 47.5% were born FTND (full tern normal delivery) at hospital and 27.5% were born through LSCS (lower segment caesarean section) followed by 25% FTND (full tern normal delivery) at home. Maximum number of patients registered in the study were residing in rural area (52.5%) while 47.5% of patients were from urban area. In the present study 65% of children were completely immunized as per national immunization program while 35% of patients were having incomplete immunization history. 55% patients had decreased appetite, 35% patients had average appetite and only 10% patients had good appetite. Among the 40 patients in both groups 65% of the patients were having regular and remaining 35% have irregular sleep pattern. Bowel habits were regular in 50% patients whereas 22.5% patients were suffering

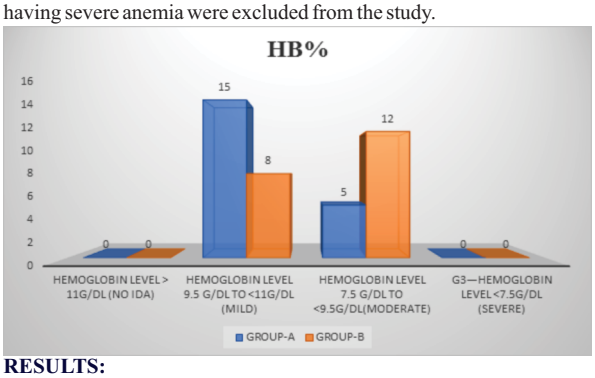
from irregular bowel habits and 27.5% patients had constipation, none of the patients had loose motions.

B. Clinical profile

Among the clinical features of *Pandu Roga* (Pallor), *Pandu Varna* was seen in 100% of the patients followed by *Daurbalya* (General weakness) in 90% of patients. *Ayasena Shwasa* (Exertion dyspnoea) by 87.5%. *Aruchi* (Loss of appetite) was found in 85% of patients. *Pindikodweshtana* (Leg cramps) was found in 45% of patients and *Akshikootshoth* (Periorbital swelling) was found in only 42.5% of patients.

Grading Of Blood Hemoglobin Level

Majority of the patients registered in the study were having mild anemia (57.5) and 42.5% have moderate anemia while the patients having severe anemia were excluded from the study.



RESULTS:

Group A

Effect of therapy on subjective parameters: -

- Statistically highly significant results were found in subjective parameters on *Panduta* and and *Akshikoot Shoth* as value of p<0.001.
- Statistically significant results were found in subjective parameters like *Ayasena Shwasa* *Daurbalya and Aruchi* as value of p<0.05 in each.
- Statistically non-significant result was found in subjective parameter *Pindikodweshtana* p>0.05

Table no. 1: Effect on clinical features - Group A

Group A	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Pallor	1.65	0.20	2.00	0.00	0.67	0.41	-4.041a	0.000053	87.88	HS
Periorbital oedema	0.45	0.05	0.00	0.00	0.51	0.22	-2.828a	0.000468	88.89	HS
Leg cramps	0.55	0.45	0.00	0.00	0.83	0.69	-1.440	0.387441	18.18	NS
Exertio dyspnea	1.15	0.65	1.00	1.00	0.67	0.49	-3.314a	0.009196	43.48	Sig
General weakness	1.15	0.50	1.00	0.50	0.49	0.51	-4.066a	0.004778	56.52	Sig
Loss of appetite	1.70	0.75	2.00	1.00	0.86	0.72	-3.714a	0.002039	55.88	Sig

Effect of therapy on objective parameters: -

- In objective parameters, statistically significant result was found in Hb% ESR, RBC Count, Hematocrit, MCV, and as MCH p<0.05
- Statistically non-significant result was found in TLC, DLC, MCHC, RDW-CV, Platelet count and MPV as p> 0.05.

Group B

Effect of therapy on subjective parameters: -

- Statistically highly significant result was found in subjective parameter *Panduta*, *Daurbalya and Aruchi* as value of p<0.001.
- Statistically significant result was found in subjective parameters like *Akshikootshoth Pindikodweshtana* as value of p<0.05 in each.

Table no.2: Effect on clinical features - Group B

Group B	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Pallor	1.95	0.30	2.00	0.00	0.69	0.47	-4.005a	0.000062	84.62	HS
Periorbital oedema	0.40	0.20	0.00	0.00	0.50	0.41	-2.000a	0.045500	50.00	Sig
Leg cramps	1.15	0.15	1.50	0.00	1.14	0.37	-3.025a	0.002485	86.96	Sig
Exertio dyspnea	1.30	0.20	1.00	0.00	0.86	0.41	-3.787a	0.000152	84.62	HS
General weakness	1.15	0.35	1.00	0.00	0.67	0.49	-3.557a	0.000375	69.57	HS
Loss of appetite	1.40	0.35	2.00	0.00	0.99	0.49	-3.384a	0.000715	75.00	HS

Table no. 3: Comparative effect of Group A and Group B on Clinical features

	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Pallor (Pandu Varna)	Group A	20	19.05	381.00	171.000	0.376
	Group B	20	21.95	439.00		
	Total	40				
Periorbital Oedema (Akshikoota Shoth)	Group A	20	22.50	450.00	160.000	0.173
	Group B	20	18.50	370.00		
	Total	40				
Leg Cramps (Pindikodweshtan)	Group A	20	15.60	312.00	102.000	0.001
	Group B	20	25.40	508.00		
	Total	40				
Exertion Dyspnea (Ayasena Swasa)	Group A	20	15.75	315.00	105.000	0.004
	Group B	20	25.25	505.00		
	Total	40				
General Weakness (Daurbalya)	Group A	20	19.35	387.00	177.000	0.464
	Group B	20	21.65	433.00		
	Total	40				
Loss of appetite (Aruchi)	Group A	20	20.03	400.50	190.500	0.784
	Group B	20	20.98	419.50		
	Total	40				

Effect of therapy on objective parameters: -

- In objective parameters, statistically significant results were found in Hb% ESR, RBC Count, Hematocrit, MCV, MCH and as p<0.05
- Statistically non-significant results were found in TLC, DLC, MCHC, RDW-CV, Platelet count and MPV as p> 0.05.

Table no.4: Effect on hematological parameters - Group A

Group A		Mean	N	SD	SE	t -Value	p -Value	% Effect	Result
Hb%	BT	9.73	20	0.91	0.20	-13.254	.000	17.37	Sig
	AT	11.42	20	0.84	0.19				
TLC	BT	7760.00	20	1807.41	404.15	-.061	.952	0.45	NS
	AT	7795.00	20	1558.84	348.57				
Neu hils trop	BT	62.80	20	5.04	1.13	.785	.442	-1.83	NS
	AT	61.65	20	3.91	0.87				
Eosi hils nop	BT	1.55	20	0.94	0.21	-.865	.398	16.13	NS
	AT	1.80	20	1.01	0.22				
Bas ls ophi	BT	0.00	20	0.00	0.00	NA	NA	0.00	NS
	AT	0.00	20	0.00	0.00				
Monocytes	BT	4.25	20	1.68	0.38	-.174	.864	2.35	NS
	AT	4.35	20	1.76	0.39				
Lymphocytes	BT	30.80	20	4.18	0.93	-1.188	.249	5.36	NS
	AT	32.45	20	3.98	0.89				
ESR	BT	16.90	20	9.49	2.12	1.091	.043	8.58	Sig
	AT	15.45	20	4.29	0.96				

Table no.5: Effect on hematological parameters - Group B

Group B		Mean	N	SD	SE	t-Value	p -Value	% Change	Result
Hb%	BT	9.18	20	1.09	0.24	-7.799	.000	22.11	Sig
	AT	11.21	20	0.62	0.14				
TLC	BT	7435.00	20	1654.11	369.87	-1.877	.076	13.92	NS
	AT	8470.00	20	1366.17	305.48				
Neut ils roph	BT	61.25	20	5.31	1.19	-.712	.485	2.12	NS
	AT	62.55	20	5.02	1.12				
Eosi ils noph	BT	1.75	20	1.02	0.23	-.972	.343	17.1	NS
	AT	2.05	20	1.36	0.30				
Baso phils	BT	0.00	20	0.00	0.00	NA	NA	0.00	NS
	AT	0.00	20	0.00	0.00				
Mon es ocyt	BT	4.40	20	2.52	0.56	-.340	.738	5.68	NS
	AT	4.65	20	1.57	0.35				
Lym ytes phoc	BT	32.35	20	5.33	1.19	.661	.517	3.09	NS
	AT	31.35	20	4.38	0.98				
ESR	BT	16.75	20	4.77	1.07	3.535	.002	11.3	Sig
	AT	14.85	20	3.73	0.83				

Table no.6: Comparative effect of Group A and Group B on hematological parameters

	Group	N	Mean	SD	SE	t-Value	P -Value	Result
Hb	Group A	20	1.69	0.57	0.13	-1.442	0.158	NS
	Group B	20	2.08	1.07	0.24			
TLC	Group A	20	2195.00	1210.69	270.72	-0.725	0.473	NS
	Group B	20	2445.00	955.58	213.67			
Neutrophils	Group A	20	5.55	3.46	0.77	-1.736	0.091	NS
	Group B	20	7.40	3.28	0.73			
Eosinophils	Group A	20	0.65	1.14	0.25	-0.716	0.478	NS
	Group B	20	0.90	1.07	0.24			
Basophils	Group A	20	0.00	0.00	0.00	NA	NA	NS
	Group B	20	0.00	0.00	0.00			
Monocytes	Group A	20	1.90	1.68	0.38	-0.904	0.372	NS
	Group B	20	2.45	2.14	0.48			
Lymphocytes	Group A	20	5.55	3.00	0.67	0.046	0.964	NS
	Group B	20	5.50	3.87	0.87			
ESR	Group A	20	3.55	4.93	1.10	0.743	0.462	NS
	Group B	20	2.70	1.38	0.31			

Table no. 7: Effect on hematological parameters - Group A

Group A		Mean	N	SD	SE	t-Value	p -Value	% Change	esult
RBC Count	BT	4.08	20	0.41	0.09	-2.165	0.043	5.25	Sig
	AT	4.29	20	0.31	0.07				
Hematocrit %	BT	34.44	20	2.16	0.48	-5.183	0.000	4.99	Sig
	AT	36.16	20	2.27	0.51				
MCV fl	BT	83.44	20	6.71	1.50	-4.796	0.000	4.43	Sig
	AT	87.13	20	5.94	1.33				
MCH pg	BT	25.56	20	1.99	0.45	-4.390	0.000	6.65	Sig
	AT	27.26	20	2.23	0.50				
MCHC g/dl	BT	32.11	20	2.08	0.47	-1.334	0.198	1.71	NS
	AT	32.66	20	2.11	0.47				
RDW-CV %	BT	32.09	20	1.04	0.23	-1.759	0.095	1.53	NS
	AT	32.58	20	1.33	0.30				
MPVfl	BT	11.64	20	1.15	0.26	0.673	0.509	1.29	NS
	AT	11.49	20	0.82	0.18				
Platelet count	BT	249250.00	20	58771.52	13141.71	-0.810	0.428	5.56	NS
	AT	263100.00	20	56031.85	12529.10				

Table no.8: Effect on hematological parameters - Group B

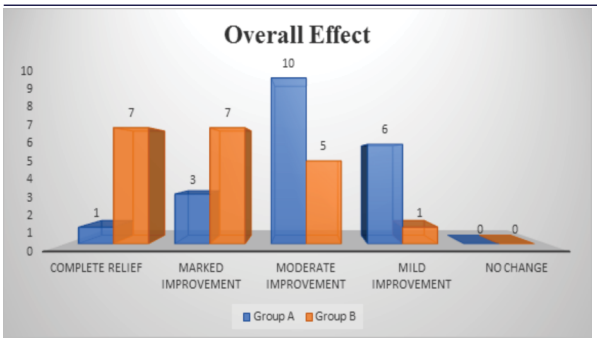
Group B		Mean	N	SD	SE	t -Value	p -Value	% Change	Result
RBC Count	BT	3.87	20	0.45	0.10	-5.716	0.000	10.18	Sig
	AT	4.26	20	0.35	0.08				
Hematocrit%	BT	34.39	20	2.35	0.53	-4.818	0.000	6.60	Sig
	AT	36.66	20	1.74	0.39				
MCV fl	BT	82.32	20	11.33	2.53	-2.352	0.030	5.33	Sig
	AT	86.70	20	5.85	1.31				
MCH pg	BT	25.03	20	3.24	0.73	-3.108	0.006	9.97	Sig
	AT	27.53	20	1.95	0.44				
MCHC g/dl	BT	32.07	20	2.40	0.54	-2.229	0.038	3.24	Sig
	AT	33.11	20	1.41	0.32				
RDW-CV %	BT	33.06	20	1.97	0.44	0.427	0.674	0.64	NS
	AT	32.85	20	1.30	0.29				
MPV fl	BT	11.70	20	0.69	0.15	0.325	0.749	0.64	NS
	AT	11.63	20	0.92	0.20				
Platelet count	BT	250800.00	20	51153.64	11438.30	-1.499	0.150	10.17	NS

Table no.9: Effect of Group A and Group B on hematological parameters: -

	Group	N	Mean	SD	SE	t -Value	p -Value
RBC count/Mill/cu.mm	Group A	20	0.33	0.36	0.08	-0.703	0.486
	Group B	20	0.40	0.30	0.07		
Hematocrit%	Group A	20	1.87	1.28	0.29	-1.287	0.206
	Group B	20	4.22	8.05	1.80		
MCV fl	Group A	20	4.08	2.96	0.66	-2.062	0.046
	Group B	20	7.16	5.99	1.34		
MCH pg	Group A	20	1.84	1.57	0.35	-3.117	0.003
	Group B	20	3.73	2.20	0.49		
MCHC g/dl	Group A	20	1.22	1.47	0.33	-1.583	0.122
	Group B	20	1.91	1.28	0.29		
RDW-CV %	Group A	20	0.94	0.94	0.21	-1.043	0.304
	Group B	20	1.39	1.69	0.38		
Platelet count	Group A	20	62750.00	43700.99	9771.84	-0.571	0.572
	Group B	20	70000.00	36304.27	8117.88		
MPV fl	Group A	20	0.64	0.77	0.17	-0.596	0.555
	Group B	20	0.78	0.66	0.15		

Table no.10: Showing comparison between percent effect on subjective parameters of group A and B.

Parameter	% Effect	
	Group A	Group B
Pallor	87.88	84.62
Periorbital Oedema	88.89	50.00
Leg Cramps	18.18	86.96
Exertion dyspnea	43.48	84.62
General Weakness	56.52	69.57
Loss of Appetite	55.88	75.00
Average % Effect	58.47	75.13



Overall effect of the therapy shows that 20% of the patients showed complete relief, 25% of the patients showed marked improvement, 37. 5% showed Moderate improvement, 17.5% showed Mild Improvement and none of the patient showed no improvement.

DISCUSSION: -

Pediatric age group is very much prone to IDA due to many physiological, psychological and social issues. Children are at growing age require increased amount of nutrients as compared to that of adults. In the present clinical study, a sample of 40 patients were selected for the study and were randomly divided into two groups (Group-A &B). Group-A was treated as trial group and was administered with *Darvyadi Leha* in *Avleha* form. Dose calculation was done as per Yogratnakar (mentioned under *Bal Rog Chikitsa Prakaran*). Group-B was treated as control group and was administered with iron syrup (4mg/kg/day) BD in between meals. Deworming of patients was done before starting the trial. The follow up was done on every one-month upto 3 months and at 7th day after the completion of treatment then the effect of treatment was observed.

CONCLUSION:

Hence, the drug *Darvyadi Leha* and conventional medicine iron syrup both have their specific role in *Pandu Roga* (IDA). *Darvyadi Leha* contains iron (*Lauha Bhasma*) and herbal ingredients (*Triphala*, *Trikatu*, and *Daruharidr, Vidang*). Herbal ingredients present in *Darvyadi Leha* might have increased the bioavailability of iron present in the formulation. Hematinic action of *Darvyadi Leha* may be due to the presence of iron contents of good bioavailability. The present clinical study clearly indicates that the herbo-mineral formulation *Darvyadi Leha* is an effective, well-tolerated, and clinically safe formulation for the treatment of IDA in children.

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