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RESEARCH ARTICLE

A CLINICAL STUDY IN THE MANAGEMENT OF PANDU (IRON DEFICIENCY ANAEMIA) WITH AN INDIGENOUS COMPOUND

Dr. Adarsh P.
Assistant Professor Department of Roga Nidana, K.J. Institute of Ayurveda and Research and Kashiba Ayurveda Hospital, Savli, Vadodara, Gujarat.

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Abstract

Ayurveda is the science of life. The definition of Swastha is equilibrium state of Dosha, Dhatu, Agni, Mala along with Prasanna Atma, Mana, Indriyas. The reason for disease to occur is Dhatu Vaishamyata. Pandu Roga is one among them which occurs due to Dhatu Vaishamyata.Pandu is described in almost all authentic Ayurvedic literatures. As the name denotes the main feature of Pandu Roga is Pandutva. According to Charaka, it is one among the RasavahaSrotodushti. Susruta has mentioned it as RaktavahaSrotodushti. 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, shortness of breath, palpitations, Koilonychia, Glossitis, Dysphagia and altered sensation of taste. The modern management of Iron Deficiency Anaemia is to find out and treat the underlying cause and to give iron to correct the Anaemia. The best preparation of oral iron is Ferrous Sulphate 100mg twice daily. But this has adverse effect. Here is a novel approach for the management of Pandu (Iron Deficiency Anaemia) without using iron in any form. Selected compound consisting of ingredients Nimba, Daruharidra, Triphala, Trikatu, Hareetaki, Shilajith, Badara does not contain iron as an ingredient thus averting the adverse effect of oral iron therapy such as fatigue, loss of appetite, weakness, breathlessness and palpitation, particularly with physical exertion and pallor of the skin and the mucous membrane.

Introduction:-

Anaemia the word has come from 'Anaimia'. 'An' means without and 'Haima' means Blood[1]. Nutritional deficiency anaemia is very common in India and iron deficiency is the commonest nutritional deficiency all over the world. Most of the people in the world are suffering from Iron Deficiency Anaemia and India is one among the nations with high prevalence of Iron Deficiency Anaemia[2]. National family health survey reveals the presence of anaemia to be 70-80%vin children, 70% in pregnant women and 24 % in adult men[3,4,5]. Pandu is described in almost all authentic Ayurvedic literatures. As the name denotes the main feature of Pandu Roga is Pandutva. According to Charaka, it is one among the RasavahaSrotodushti. Susruta has mentioned it as RaktavahaSrotodushti. Pitta Dosha vitiation is the main causative factor which inturn vitiates Vata and KaphaDosha too. Rakta, Mamsa and Twak are

Corresponding Author: -Dr Adarsh.P
Address**: -**Assistant professor Department of RogaNidana, K.J. Institute of Ayurveda and Research and Kashiba Ayurveda Hospital, Savli, Vadodara, Gujarat.

also vitiated[6,7]. AlpaRakta, AlpaMeda, Ojokshaya, Shihtilendriya and Vaivarnyata of Sareera are the PratyatmaLakshana of Pandu Roga[6,7].

The causes of Iron Deficiency Anaemia are insufficient dietary intake and improper absorption of iron which causes symptoms such as feeling of weakness, tiredness, shortness of breath, palpitations, koilonychia, glossitis, dysphagia and altered sensation of taste[8,9]. The modern management of Iron Deficiency Anaemia is to find out and treat the underlying cause and to give iron to correct the anaemia. The best preparation of oral iron is Ferrous Sulphate which is given at a dose of 100mg twice daily. But this has many adverse effects like nausea, diarrhoea, dyspepsia, constipation etc.

Ayurveda being holistic medicine advises that all diseases are due to malfunction of Agni (metabolism). If metabolism is good everything gets digested and assimilated, which is necessary for the sustaining the health. Both Ayurveda and contemporary science accepts the fact that derangement of Agni (metabolism) is the root cause of the disease. As a result of weakened Agni an intermediate product of metabolism called Ama is formed. This Ama causes diseases like Pandu.

Pandu being a SantarpanajanyaVikara, requires TeekshnaOushadies like Loha to break the Samprapthi[10]. Contemporary science also accepts the facts that disturbed absorption along with dietary insufficiency is the root cause for Iron Deficiency Anaemia. Even though Ayurveda and modern science utilizes iron in Pandu (Iron Deficiency Anaemia) but intentions are grossly different.

Here is a novel approach to manage Pandu (Iron Deficiency Anaemia) without using iron as a direct supplement. Selected compound consisting of ingredients Nimba, Daruharidra, Punarnava, Triphala, Trikatu, Hareetaki, Shilajith, Badara does not contain iron as an direct ingredient thus averting the adverse effect of oral iron therapy such as constipation, fatigue, loss of appetite, weakness etc[11,12].

Aims and Objectives:-

The present study was taken up with following aims and objectives.

Objectives of the study:

1. To evaluate the efficacy of Indigenous Compound in the management of Pandu Roga (Iron Deficiency Anaemia).
2. To compare the efficacy of herbomineral preparation with Ferrous Sulphate.

Methodology: -

Clinical source:

Patient of either sex attending the OPD & IPD of A.L.N. Rao Memorial Ayurvedic Medical College & Hospital Koppa along with its associated hospitals and MSDM Government hospital, Koppa were selected for the study. The study was conducted from December 2014 to August 2015. Subjects diagnosed with Pandu (Iron Deficiency Anaemia) were incidentally selected and randomly categorized into two groups, each consisting at least 20 subjects using simple randomization based on incidence. Complete details of the clinical trial and the rights of the participant were explained and informed consent was obtained from each participants or guardians of the participants. From the Institutional Ethical Committee clearance has been obtained for the study.

Pharmaceutical source:

Capsule Indigenous Compound containing powders of Nimba (Azadirachtaindica)-50mg, Daruharidra (Beriberisaristata)- 75mg, Badara (Zizyphusjujuba)- 50gm, Punarnava (Boerhaaviadiffusa)- 75mg, Shilajith- 50mg, Harithaki (Terminalia chebula)- 100mg, Trikatu- 50gm (powders of Sunti- Zingiber officinale, Maricha- Piper nigrum, Pippali- Piper longum), Triphala-50 gm (Amalaki - Emblica officinalis, Haritaki- Terminalia chebula, Vibheetaki- Terminalia bellerica) was procured from Capro Labs India Pvt. Ltd , which is marketed in the name Hb CAP Capsules.. The control drug ferrous sulphate tablets of 100mg was procured from a reputed pharmaceutical company.

Table 1:- Ingredients of the trial drug.

Sl. No	Ingredients	Part used	Quantity

1	Nimba	Bark	50mg
2	Daruharidra	Stem	75mg
3	Punarnava	Wholeplant	75mg
4	Shilajith		50mg
5	Harithaki	Fruit	100mg
6	Trikatu	Rhizome, fruit	50gm
7	Triphala	Fruit	50gm
8	Badara	Fruit	50gm

Study design:
Randomized controlled clinical trial.

Criteria for selection of patients:
Inclusion Criteria:
Patients diagnosed with Pandu (Iron deficiency Anaemia) from either sex within the age group of 20 –60 years and Hb% within the rangeof 7-12gm/dl in males and 7-11gm/dl in females was selected[13].

Exclusion Criteria:
Patients with history of systemic diseases like diabetes mellitus and hypertension, pregnant and lactating women, subjects with abnormal hemopoiesis like megaloblastic anaemia, unusual haemolysis due to red cell membrane defects, hereditary spherocytosis, hereditary elliptocytosis, and malaria, auto immune haemolyticanaemia, unusual blood loss like gastro intestinal bleeding, physical trauma, haemoglobinopathies like sickle cell anaemia, leukemia, thalassaemia and patients with infectious diseases were excluded.

Laboratory investigations:
Following laboratory blood investigations was used in the study Hb%, MCH, MCV, PCV, MCHC for diagnosis and assessment of Iron Deficiency Anaemia.

Table 2:- Interventions.

	Group A	**Group B** (Standard control)
Sample Size	20	20
Medicine	Cap. Indigenous compound	Tab. Ferrous sulphate
Dose	500mg, twice daily (after food)	100mg, twice daily (after food)
Anupana	Ushnajalaq.s	Ushnajalaq.s
Duration	8 weeks	8 weeks
Follow up	4 weeks	4 weeks

During the period of study the patients will be advised to follow Pathyapathya strictly.

Assessment of Outcomes:
Subjective Parameters:
Subjective measures like Dourbalya, Srama, Aarohanaayasa, Panduta,Bhrama, Hrudrava, Karnakshweda, Aruchi, Agnimandyam, Shunakshikutashotha, Shirnalomata, Pindikodweshtanam, Tama-darsan, Hridayaspandanadhikya, and Gauravam were graded according to gradations taken from the WHO DFC project work shop conducted in Jamnagar 2010 and assessed pre and post test.

Objective Parameters:
Objective Parameters like Hb%, MCH, MCV, PCV, MCHC, Serum ferritin and TIBC (in selected cases) are assessed pre and post test. Assessment of objective parameters was done based on improvement in haemoglobin percentage, PCV, MCV and MCH post-test.

Table 3:- Assesment Criteria.

Subjective Parameters			
No	**Parameters**	**Range**	**Score**
1.	**Daurbalyam**	No Daurbalyam-	0
		After heavywork	1
		After lightwork	2
		Always present	3
2.	**Srama**	No Srama	0
		After heavy work	1
		After light work	2
		Always present	3
3	**Arohanaayasa**	Not present	0
		Present after 20 minutes of walking	1
		Present after 10 minutes of walking	2
		Present after 5 minutes of walking	3
4	**Pandutha (Pallor):**	Absent	0
		Visible only in the Sclera	1
		Visible in sclera & nail both	2
		Visible in the above two and Face	3
5	**Bhrama**	Not Present	0
		After heavy work, relieved soon & tolerate	1
		After Moderate work relieved later & tolerate	2
		After little work relieved later	3
		After little work relieved later but beyond tolerate	4
		Bhrama even in resting condition	5
6	**Hrudrava**	No Hrudrava	0
		After heavy work	1
		After light work	2
		Always present	3
7	**Karnakshweda**	Absent	0
		Occasional & Tolerable	1
		Occasional & Non-Tolerable	2
8.	**Aruchi**	Not present	0
		Willing towards specific taste only	1
		Willing towards one taste only	2
		Will not appreciate taste of food	3
9.	**Agnimandyam**	No Agnimandya	1
		Delayed digestion of heavy meals	2
		Delayed digestion of light meals	3
		Cannot digest even light meals	4
10	**ShunakshikutaShotha**	Absent	0
		Mild	1
		Moderate	2
11	**Shirnalomata**	No Hair Fall	0
		Hair fall during combing the wet hair or after oiling the hair & combing	1
		Hair fall during washing the hair and normal combing	2
		Hair fall without combing	3
12	**Pindikodweshtanam**	Absent	0
		After heavy work	1
		After moderate work	2
		Only at night but beyond tolerate	3
13	**Tama-darsana**	Nil	0
		Rare TamaDarśana for short duration	1

		Rare TamahaDarśana for small duration leads to Bhrama	2
		Frequent TamahaDarśana for small duration leads to Bhrama	3
14	**HridayaSpandanadhikya**	Absent	0
		Present only during some exercise that subsides itself on rest	1
		Present during the normal routine activities that subsides itself on rest	2
		Present during the normal routine activities but doesn't subside on rest	3
15	**Gauravam**	Absent	0
		Feeling Gauravam once or twice in a day without affecting the normal routine work	1
		Feeling Gauravam throughout the day without affecting the normal routine work	2

Sample size:
Out of 60 patients of Pandu (IDA) screened for eligibility, 47 were incorporated in to clinical trial. Among them, seven failed to follow-up hence declared as dropped out. None were withdrawn in the middle of the trial duration.

Statistical Methods:-
The data was statistically analysed using paired and unpaired Students, T test.

Observation and Results:-
In the study more than 60 patients diagnosed with Pandu (Iron Deficiency Anaemia) were screened for the eligibility and 47 were selected. Seven were dropped out for nonspecific reasons especially failure to follow up. 20 patients completed the study in each group. The observations were made on the basis of clinical findings.

Results:-
Following are the results obtained in the patients of Pandu Roga on administration of Capsule Indigenous Compound per the defined protocol. Parameters of assessment were scored at base line (BT) and after completion of the treatment. The data was processed for student's t test using Sigma stat 3.5. The results have been presented below.

Effect of therapyin subjective parameters of assessment of Pandu Roga

Effect of therapy on Daurbalyam:
In the subjective parameter of Daurbalyam, Capsule Indigenous Compound drug exhibited 66.6% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 64.4% improvement.

Table 4:- Effects of therapy on Daurbalyam.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	2.25	0.75	66.6	0.163	0.045	6.380	<0.001	Highly significant
Group B	2.25	0.8	64.4	0.188	0.042	6.355	<0.001	Highly significant

Effect of therapy on Srama:
In the subjective parameter of Srama, Capsule Indigenous Compound drug exhibited 58.1% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 57.1% improvement

Table 5:- Effects of therapy on Srama.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	2.15	0.9	58.1	0.247	0.055	5.922	<0.001	Highly significant
Group B	2.25	0.95	57.1	0.265	0.06	5.402	<0.001	Highly significant

Effect of therapy on ArohanaAayasa:
In the subjective parameter of ArohanaAayasa, Capsule Indigenous Compound drug exhibited 47.6% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 56% improvement

Table 6:- Effects of therapy on Arohanaaayasa.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	2.1	1.1	47.6	0.138	0.03	5.766	<0.001	Highly significant
Group B	2.3	1	56	0.208	0.047	6.110	<0.001	Highly significant

Effect of therapy on Pandutwa:
In the subjective parameter of Pandutwa, Capsule Indigenous Compound drug exhibited 57.1% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 45.8% improvement

Table 7:- Effects of therapy on Pandutwa.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	2.45	1.05	57.1	0.489	0.109	12.337	<0.001	Highly significant
Group B	2.4	1	45.8	0.265	0.059	11.637	<0.001	Highly significant

Effect of therapy on Bhrama:
In the subjective parameterBhrama, Capsule Indigenous Compound drug exhibited 64.5% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 70% improvement.

Table 8:- Effects of therapy on Bhrama.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	2.4	0.85	64.5	0.202	0.045	5.66	<0.001	Highly significant
Group B	2.5	0.75	70	0.002	0	6.449	<0.001	Highly significant

Effect of therapy on Hrudrava:
In the subjective parameterHrudrava, Capsule Indigenous Compound drug exhibited 61.5% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 59% improvement.

Table No. 8:- Effects of therapy on Hrudrava.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	1.95	0.75	61.5	0.276	0.062	5.724	<0.001	Highly significant
Group	2.2	0.9	59	0.401	0.0899	5.294	<0.001	Highly

B								significant

Effect of therapy on Karnakshweda:
In the subjective parameterKarnakshweda ,Capsule Indigenous Compound drug exhibited 52% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug also showed 52% improvement.

Table 10:- Effects of therapy on Karnakshweda.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	0.95	0.45	52	0.109	0.0239	3.851	<0.001	Highly significant
Group B	1.05	0.5	52	0.116	0.0259	3.468	<0.001	Highly significant

Effect of therapy on Aruchi:
In the subjective parameterAruchi ,Capsule Indigenous Compound drug exhibited 94% improvement after 60 days of treatment which is statistically highly significant with p value <0.001.Control drug also showed 94% improvement.

Table 11:- Effects of therapy on Aruchi.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	1.75	0.1	94	0.652	0.1437	7.065	<0.001	Highly significant
Group B	1.8	0.1	94	0.671	0.1502	6.974	<0.001	Highly significant

Effect of therapy on Agnimandya:
In the subjective parameterAgnimandya, Capsule Indigenous Compound drug exhibited 71% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 57% improvement.

Table 12:- Effects of therapy on Agnimandya.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	2.3	0.65	71	0.109	0.025	10.126	<0.001	Highly significant
Group B	2.25	.55	57	0.206	0.046	8.643	<0.001	Highly significant

Effect of therapy onShunakshikutaShotha:
In the subjective parameter ShunakshikutaShotha, Capsule Indigenous Compound drug exhibited 81% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 76% improvement.

Table 13:- Effects of therapy on ShunakshikutaShotha.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	1.65	0.3	81	0.019	0.004	8.897	<0.001	Highly significant
Group B	1.7	0.4	76	0.158	0.0317	7.681	<0.001	Highly significant

Effect of therapy onSirnalomata:
In the subjective parameter Sirnalomata, Capsule Indigenous Compound drug exhibited 71.7% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 68% improvement.

Table 14:- Effects of therapy on Sirnalomata.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	2.3	0.65	71.7	0.064	0.015	7.755	<0.001	Highly significant
Group B	2.5	0.8	68	0.138	0.031	7.678	<0.001	Highly significant

Effect of therapy onPindikodweshtanam:
In the subjective parameter Pindikodweshtanam, Capsule Indigenous Compound drug exhibited 83.3% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 73.8% improvement.

Table 15:- Effects of therapy on Pindikodweshtanam.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	2.4	0.4	83.3	0.308	0.069	8.779	<0.001	Highly significant
Group B	2.45	0.65	73.8	0.183	0.041	9.726	<0.001	Highly significant

Effect of therapy onTama- Darshanam:
In the subjective parameter Tama- Darshanam ,Capsule Indigenous Compound drug exhibited 100% improvement after 60 days of treatment which is statistically highly significant with p value <0.001.Control drug showed 87.5% improvement.

Table 16:- Effects of therapy on Tama- Darshanam.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	0.95	0	100	0	0	12.728	<0.001	Highly significant
Group B	0.8	0.1	87.5	.366	0.447	10.376	<0.001	Highly significant

Effect of therapy onHrudayaspandanadhikya:
In the subjective parameter HrudayaSpandanadhikya, Capsule Indigenous Compound drug exhibited 50% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 55% improvement.

Table 17:- Effects of therapy on HrudayaSpandanadhikya.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	2.4	1.2	50	0.382	0.0857	6.201	<0.001	Highly significant
Group B	2.7	1.2	55	0.408	0.0912	9.464	<0.001	Highly significant

Effect of therapy onGaurava: In the subjective parameter Gaurava, Capsule Indigenous Compound drug exhibited 45.5% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 45% improvement.

Table 18:- Effects of therapy on Gaurava.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	1.65	0.9	45.5	0.366	0.0819	10.376	<0.001	Highly significant
Group B	1.85	1	45	0	0		<0.001	Highly significant

Effect of therapy onHb:
In the subjective parameter Hb, Capsule Indigenous Compound drug exhibited 26.5% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 16% improvement.

Table 19:- Effects of therapy on Hb.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	9.38	12.050	26.5	0.894	0.199	9.44	<0.001	Highly significant
Group B	9.34	10.83	16	0.586	0.131	8.007	<0.001	Highly significant

Effect of therapy onPCV:
In the subjective parameter PCV, Capsule Indigenous Compound drug exhibited 16% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 11% improvement.

Table 20:- Effects of therapy on PCV.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	33.050	38.200	16	2.308	0.42	8.733	<0.001	Highly significant
Group B	33.300	36.900	11	1.5	0.33	7.657	<0.001	Highly significant

Effect of therapy onMCV:
In the subjective parameter MCV, Capsule Indigenous Compound drug exhibited 12% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 8% improvement.

Table 21:- Effects of therapy on MCV.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	71.80	80.44	12	2.401	0.567	11.147	<0.001	Highly significant
Group B	71.80	77.32	8	2.301	0.515	7.451	<0.001	Highly significant

Effect of therapy onMCH:
In the subjective parameter MCH, Capsule Indigenous Compound drug exhibited 24.3% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 13% improvement.

Table 22:- Effects of therapy on MCH .

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	20.41	25.39	24.3	1.61	0.724	9.702	<0.001	Highly significant

Group B	20.12	22.69	13	1.122	0.250	7.244	<0.001	Highly significant

Effect of therapy onMCHC:
In the subjective parameter MCHC, Capsule Indigenous Compound drug exhibited 21.3% improvement after 60 days of treatment which is statistically highly significant with p value <0.001. Control drug showed 5% improvement.

Table 23:- Effects of therapy on MCHC.

	BT (Mean)	AT (Mean)	Change in %	SD	SE	t	P	Remarks
Group A	28.44	31.06	21.3	2.618	0.585	3.137	<0.001	Highly significant
Group B	28.049	29.341	5	0.891	0.311	2.888	<0.001	Highly significant

Comparative assessment:
Both the trial drug Hb CAP and control drug Ferrous Sulphate yielded statistically significant result on comparative assessment of subjective parameters like Hb%, PCV, MCV, MCH, MCHC and insignificant results in objective parameters which are reported below.

Table 24:- Comparative effect of therapy in Hb%.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
2.87	1.485	0.929	0.249	6.691	<0.001	Highly significant

Table 25:- Comparative effect of therapy in PCV.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
5.1	3.6	2.283	0.510	2.939	0.008	Significant

Table 26:- Comparative effect of therapy in MCV.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
8.582	5.526	4.715	1.050	2.898	0.009	Significant

Table 27:- Comparative effect of therapy in MCH.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
5.108	2.574	2.644	0.591	4.287	<0.001	Highly significant

Table 28:- Comparative effect of therapy in MCHC.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
3.373	1.538	2.470	0.552	3.324	0.004	Significant

Table 29:- Comparative effect of therapy in Daurbalyam.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.45	1.4	0.759	0.170	0.291	0.77	Non significant

Table 30:- Comparative effect of therapy in Srama.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.3	1.3	0.67	0.15	1.00	0.330	Non significant

Table 31:- Comparative effect of therapy in ArohanaAayasa.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.25	1.35	0.910	0.200	1.220	0.234	Non significant

Table 32:- Comparative effect of therapy in Pandutwa.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.5	1.4	0.640	0.140	0.000	1.000	Non significant

Table 33:- Comparative effect of therapy in Bhrama.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.6	1.65	1.310	0.290	0.17	0.867	Non significant

Table 34:- Comparative effect of therapy in Hrudrava.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.15	1.15	1.110	0.257	0.615	0.546	Non significant

Table 35:- Comparative effect of therapy in Karnakshweda.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
0.6	0.5	0.898	0.206	0.766	0.454	Non significant

Table 36:- Comparative effect of therapy in Aruchi.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.45	1.55	1.514	0.357	0.156	0.878	Non significant

Table 37:- Comparative effect of therapy in Agnimandya

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.55	1.7	1.106	0.254	0.000	1.000	Non significant

Table 38:- Comparative effect of therapy in ShunakshikutaShotha.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.25	1.35	0.577	0.132	0.000	1.000	Non significant

Table 39:- Comparative effect of therapy in Sirnalomata.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.35	1.65	1.167	0.292	0.643	0.530	Non significant

Table 40:- Comparative effect of therapy in Pindikodweshtanam\.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.9	1.9	1.468	0.328	0.152	0.881	Non significant

Table 41:- Comparative effect of therapy in Tama- Darshanam.

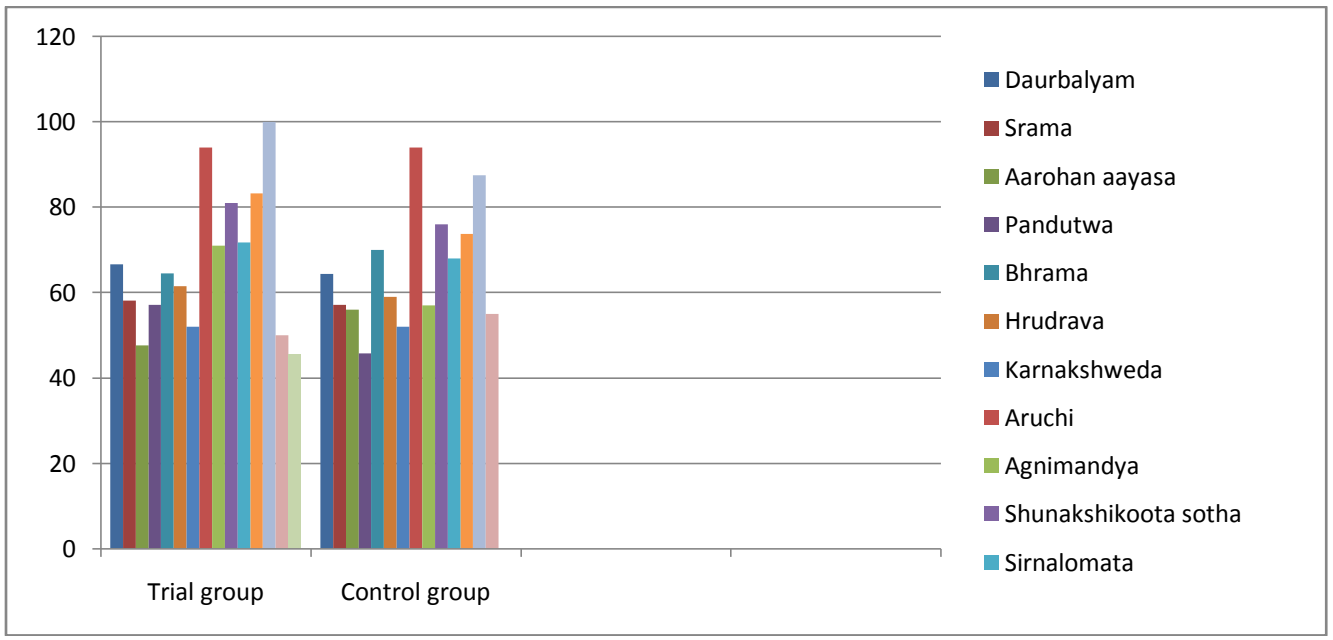
Mean Group A	Mean group B	SD	SE	t	P	Remarks
0.85	0.95	0.447	0.100	-1.000	0.330	Non significant

Table 42:- Comparative effect of therapy in HrudayaSpandanadhikya.

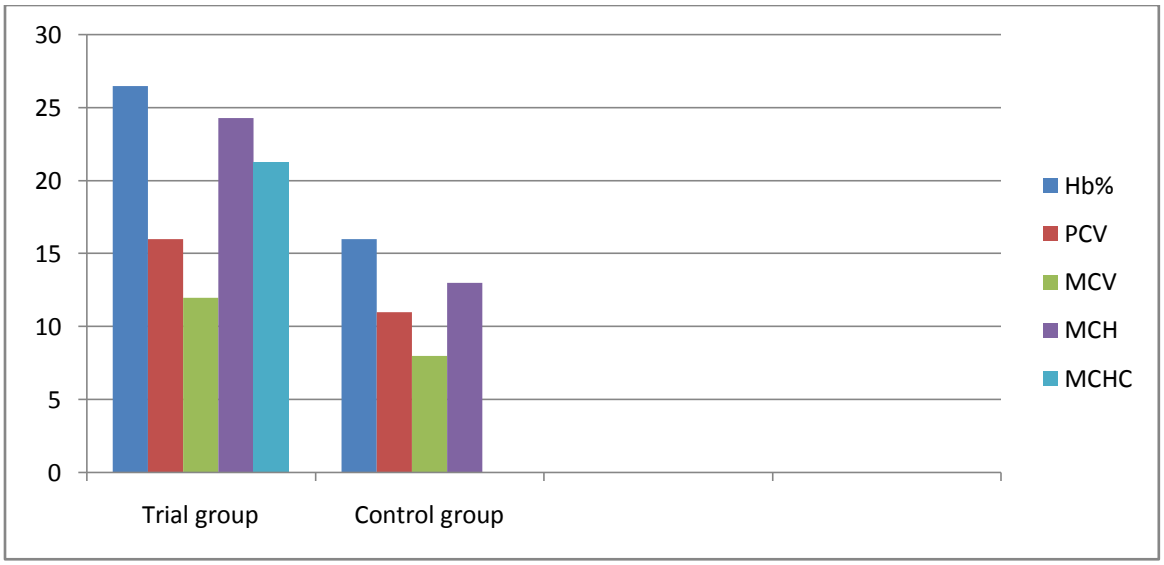
Mean Group A	Mean group B	SD	SE	t	P	Remarks
1.3	1.5	1.542	0.345	0.580	0.569	Non significant

Table 43:- Comparative effect of therapy in Gaurava.

Mean Group A	Mean group B	SD	SE	t	P	Remarks
0.85	0.95	0.447	0.100	1.000	0.330	Non significant



Graph 1:- Percentage wise improvement of subjective parameters in each group.



Graph 2:- Percentage wise improvement of objective parameters in each group.

Discussions:-

Forty-Seven patients were eligible for the study in which 7 were dropped in between. The study was conducted on 40 patients, 20 patients were put on trial group rest 20 patients in control group selected from the OPD & IPD of A.L.N. Rao Memorial Ayurvedic Medical College and hospital, Koppa along with its associated OPDs. For the optimum dose fixation patients within the age group of 20 to 60 were selected because the dosage varies for Bala and Vruddha. The range of haemoglobin for the selected patients was between 7-12g/dl in males and 7-11g/dl in females because haemoglobin below 7gm/dl needs emergency intervention[13]. Maximum numbers of patients in the study were observed between the ages 20 to 40. It might be due to heavy work and low food intake and menstruation in females and constant hard work and mental tension in males[14]. 95% of patients in the trial group and 90% in control group were women this might be due to fewer intakes of iron, menstrual bleeding, mental tension and malnutrition[14]. 50% of the patients were graduates in both groups and remaining 50% belong to illiterate, primary school and high school. This might be due to less awareness regarding health and disease[14]. 55% of subjects from trial group and 60% from control group were vegetarians followed by mixed diet. Vegetarians are prone to iron deficiency anaemia because iron salts in vegetables are less absorbed in GIT[15]. Majority of patients were from poor class 50% of subjects in trial and 60% in control group were from poor class. This might be due to the unavailability of nutritious food and unhygienic conditions[14]. 50% of patients in trial group and 60% in control group were addicted to tea, 35% and 25% of patients respectively in etc group were addicted to coffee. Rests of the patients were addicted to smoking and alcohol. The phenols in tea reduce the absorption of iron from GIT[16]. Smoking and alcohol affect the digestive process leading to less absorption of iron from GIT. The trial drug as well as control drug yielded statistically highly significant results in Dourbalya, Srama, Aarohanaayasa, Panduta,Bhrama, Hrudrava, Karnakshweda, Aruchi, Agnimandya, Shunkshikutashotha, Sirnalomata, Pindikodweshtanam, Tamaha-darsana, Hridayaspandanadhikya, and Gouravawith $p<0.001$ with 95% confidence interval. Both yielded statistically highly significant results with p value <0.001 in objective parameters like Hb %, PCV, MCV, MCH, and MCHC also. In objective parameters trial drug percentage wise showed marginally better improvement than control drug.

Discussion regarding the probable mode of action of Indigenous Compound Drug:

In Pandu Roga qualitative de-arrangemnt of Pitta Dosha occurs. Kapha and VataDosha also have important role in the manifestation of Pandu Roga. Agni also has an important role in the manifestation of Pandu Roga. So, the drug should be analysed based on its Tridoshahara property along with its action on Agni, Srotu sand Dhatus. If we analyse the ingredients of Indigenous Compound Drug on basis of Rasa, predominance of Tiktha, Kashaya and MadhuraRasa which is followed by Katu Rasa. Tikta and Kashaya Rasa combination might have helped to pacify the Pitta[17]. Kashaya, Tiktha and Katu Rasa predominance might have helped to remove the Srotorodha. These Rasas might have helped to pacify the KaphaPradhanaLakshanas of Pandu Roga and Agni Mandhya. Most of the ingredients of Indigenous Compound Drug are having LaghuRookshaGuna which might have helped to reduce Srotorodha and Pitta Samana. RookshaGuna might have reduced the Drava Guna of Pitta thereby increasing the Jataraagni. Few drugs have Guru Guna which might have helped to pacify Pitta. Most of the ingredients present in

Indigenous Compound Drug are having UsnaVeerya which probably have pacified Kapha, Vata predominant Lakshnas of Pandu and also cleared Srotorodha. If we analyze the Vipaka of the drugs present in Indigenous Compound Drug most of them are having Madhura Vipaka so it might be helpful in pacifying the Pitta and VataLakshnas. Most of the drugs in Indigenous Compound Drug are having Kapha Pitta Hara properties which are responsible mainly for the symptoms of Pandu Roga. Few drugs are having Vata Hara property which might have pacified deranged Vata. If we analyse the overall effect of the drug it is found to be having Tridosha Hara properties. The drug is having more Tikta, Kashaya and Madhura Rasa, LaghuRookshaGuna, UshnaVeerya and KaphaVataSamana properties which might have pacified Agnimandhya, Srotorodha, KaphaVataSamana, and restoring PrakrutaGunas of Pitta.

Effect of Indigenous Compound Drug on Hb, PVC, MCV, MCH, MCHC:
It is found that INDIGENOUS COMPOUND DRUG has significantly increased the Hb% as well as other red blood cells indices PVC, MCV, MCH, MCHC as observed in the clinical study but the exact action of the trial drug in the parameters could not be explained because pharmacological studies, chemical analysis, were not taken due to practical limitation. It is found that NimbaTwak is rich in iron content and vitamin B12[18]. The combination of NimbaTwak and Amalaki which is rich in vitamin C might have enhanced the percentage of red cell indices such as Hb, PCV, MCV, MCH, MCHC. Daruharidra has got hepatoprotective, immunomodulation and cardiotonic action[19]. Fruits of Badara are very rich in vitamin C, antioxidants, iron, vitamin B12 and it is stated that a single fruit contains enough vitamins advised by WHO for an adult. It has also got hepatoprotective, immunomodulation and cardiotonic action[20]. Punarnava contains iron; it has also got hepatoprotective immunomodulation and cardiotonic action[21]. Pipali is rich in vitamin C and it has hepatoprotective immunomodulation and cardiotonic action[22]. Pipali also enhances absorption in small intestine. Maricha enhances the absorption of iron in small intestine and is rich in vitamin C and B complex[23]. Shunti is rich in vitamin B complex, vitamin C and has got hepatoprotective immunomodulation and cardio tonic action. Minimum quantity of Shunti in diet has increased absorption in GIT and relieved constipation[24]. Amalakiis very rich source of vitamin C, and iron. It has got hepatoprotective and cardio-protective action[25]. Research works showed that Haritaki has enhanced absorption in small intestine[26]. Vibheetaki is having antioxidants, vitamin C, B complex and iron. It also showed hepatoprotective action[27]. Shilajit contains vitamin C, B complex, iron and other metals in trace quantities. Moreover, it is found that if Shilajit is given along with vitamin C or any minerals it enhances the bioavailability of that minerals.

Liver plays an important role in iron metabolism. Iron is stored in the liver as ferritin and hemosiderin which is utilized for the synthesis of new haemoglobin. Bile is a necessary factor for the absorption of iron from the small intestine. Gastric juices convert ferrous iron to ferric iron which is transported by a protein called ferroportin. This ferric iron combines with globin and it is released into the blood. This cycle is governed by liver enzyme called apotransferin released through bile. If we analyse the drugs in the Cap Indigenous Compound most of the drugs are hepatoprotective, hepato-stimulant in action which might have enhanced bile secretion and the absorption of iron from GIT.

Drugs like Nimba, Punarnava, Vibheetaki, AmalakiandShilajit has iron in good quantity and drugs like Hariaki, Pipali, Maricha and Shunti has enhanced intestinal absorption and motility, relieving constipation. Vitamin C present in the drugs might have enhanced iron absorption and might have prevented the formation of insoluble iron compounds and reduction of ferric iron to ferrous iron. Presence of Silajith might have increased the bio availability of iron and vitamins in this combination, which might have enhanced the action of the drug.

Conclusion:-

Anaemia is very common in India and iron deficiency is the commonest nutritional deficiency all over the world. According to WHO, over one third of the world's population suffers from anaemia, mostly due to iron deficiency. India continues to be one of the countries with very high prevalence.Indigenous Compound drug has beensubjected to a clinical trial on 20 patients sufferingfrom Iron Deficiency Anaemia. From the present clinical study, it is evidentthat the Indigenous Compound drug which is well tolerated and clinically safe is aneffective and better alternative for ferrous sulphate which is having much adverse effect for the management of Iron Deficiency Anaemia.

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