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CLINICAL EVALUATION OF THE EFFICACY OF NISHA LAUHA AND PHALA-TRIKADI KWATH IN THE MANAGEMENT OF PANDU WSR TO IRON DEFICIENCY ANAEMIA

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ABSTRACT

The commonest nutritional disorder present throughout worldwide is Iron deficiency but its prevalence is higher in developing countries. Anaemia is defined as a haemoglobin concentration in blood below the lower limit of the normal range for the age and sex of the individual. The study was design in controlled, non blind, randomized and hospital based study. Study was done in two groups A and B for 60 days. *Nisha Lauha* (500 mg in capsule form) and *Phalatrikadi Kwath* (40 ml) in twice a day was given in group A before meal and dried ferrous sulphate in thrice a day was given in group B after meal as a control group. Outcome measures was based on clinical features, Hb, TRBC, PCV, MCV, MCH, MCHC, peripheral blood film, TIBC, Serum Iron. After trial results show that highly significant improvement in laboratory and subjective parameters in both the groups (except in TIBC improvement was significant in group B). Finally concluded that both the trial drugs are effective in the management of *Pandu Roga.*

Key Words: Anemia, Haemoglobin, Dried ferrous Sulphate.

INTRODUCTION

Anaemia is a public health problem worldwide. The U.N.'s millennium Development Goal of 2000, has set date of 2015, to eradicate anemia. The two challenges poverty and hunger are confronting Govt. of India's resolve to fight nutritional deficiency anaemia. Among the nutritional deficiency disorders, Iron deficiency is at the top. About 4-5 billion people are affected by it, accounting for 66-80% of the world's population. According to National Nutritional Anaemia Control Programme (NNACP), 50% of the Indian population is suffering from anaemia.

Pandu Roga is characterized by pallor of body which resembles with 'anemia' of modern science, in which there is reduction in number of RBCs per cu mm of blood and decreased concentration of Hb in RBCs resulting in pallor and other symptoms. Numerous side effects like gastric irritations, nausea, vomiting, constipation, bad taste, teeth discoloration are produced by modern drugs. So taking all these facts into consideration this study was planned and carried out with two common classical drugs– "*Nisha Lauha* and *Phalatrikadi Kwath"* were selected to get an effective remedy for anaemia.

AIMS AND OBJECTIVES:

- To assess the clinical efficacy Of *Nisha Lauha* and *Phalatrikadi Kwath* in the management of *Pandu* With Special Reference to Iron Deficiency Anaemia.
- To assess the clinical safety of *Nisha Lauha* and *Phalatrikadi Kwath* in patients of Iron Deficiency Anaemia.
- To compare the efficacy of *Nisha Lauha* and *Phalatrikadi Kwath* with Ferrous sulphate.

Ethics: Institutional Ethics committee's approval was taken for the randomized, controlled group clinical study.

Selection of Cases: The study was a controlled, non blind, randomized, clinical trial using pretest-posttest design and the study population was collected from the OPD and IPD of P.G. Department of *Kayachikitsa* at *Arogyashala*, National Institute of Ayurveda and SSBH, Jaipur (Raj.). The study was conducted on 30 clinically and pathologically diagnosed patients of Anaemia. Screened and registered patients were randomly divided into two groups. **Group A -** This group of 15 patients were given the trial drug *Nisha Lauha* and *Phalatrikadi Kwath.* **Group B** - This group of 15 patients were given the control drug Dried Ferrous Sulphate.

Diagnostic criteria adopted: Inclusion Criteria:

- Patients of either sex aged between 15 to 55 years.
- Patients with Hb 6-11gm % in females &6-12gm % in males.
- Patients willing and able to carry out treatment for 2 months.
- Patients willing to sign consent form.

Exclusion Criteria:

- Patients below 15 yrs & above 55 yrs. of age.
- Pregnant ladies.
- Patients suffering from malignant disorders.
- 4.Hb. < 6 gm %
- Patients suffering from serious diseases such as IHD, CCF.
- Anaemia due to causes other than iron deficiency.
- Patients suffering from chronic disorders like RA, CRF, Hypothyroidism, Hyperthyroidism, Hepatic dysfunction, Tuberculosis.
- Hypersensitivity to any of the trial drugs or their ingredients.

Side effect evaluation criteria:

To rule out the possible adverse effect of studied drugs clinical criteria was adopted and documented in AEEF (Adverse Effect Evaluation Format-AEEF) during the course of the study. These were prepared by the pharmacy of NIA, Jaipur

Trial drug: For the management of anemia *Nisha Lauha* and *Phalatrikadi Kwath* were used to assess their efficacy. Both these formulations were prepared by the pharmacy of National Institute of ayurveda, Jaipur. Ferrous Sulphate was purchased from the market.

Dose and duration of trial drugs: *Nisha lauha* (*Haritaki, Amalaki, Vibitaki, Haridra, Kutki, Daruharidra* in equal ratio *and Lauha Bhasma* in six ratio) have a dose 500 mg (1 cap of 500 mg) twice daily and *Phalatrikadi kwath* (*Haritaki, Amalaki, Vibitaki, Kutki, Gudichi, Vasa, Nimbha, Bhunimbh)* have a dose 40 ml twice daily by orally before taking meal with Anupana of Madhu. Ferrous Sulphate had a dose of 200 mg thrice a day by orally after taking meal with water. Duration of trial was for 60 days.

Assessment criteria: Clinical assessment:

Patients were assessed on different parameters for obtaining the effect of therapies. Clinical signs and symptoms like Palpitation, Dyspnoea, Fatigue, Vertigo, Weakness, Pallor, Brittle nails, Ankle edema, Smooth tongue and Loss of appetite were assessed on the basis of scoring (grading) system (Source: Criteria 1 to 9 & 11 adopted from Management of Pandu in *Amavata*, Developed by T. K. Mondal, B. C. Jana, & N. C. Dash *Aryavaidyan* Journal Vol. XXIV No. 4 Mar July 2011; Page 232-235:4th day).

Laboratory Assessment: Blood – HB, TLC, DLC, ESR, TRBC, PCV, MCV, MCH, MCHC, Peripheral blood film (PBF), TIBC and Serum Iron.

Observation and Results: A total of 30 patients were registered and completed the trial. Out of 30 patients 40 % were in the age group

of 16 – 25 yrs, 66 % were females, 90 % were belongs to Hindu religion, 53 % were students, 53 % were married, 77 % vegetarian. Disease Onset wise Distribution profile showed that there was chronic onset in 80% patients and nutritional status wise distribution data showed that the maximum no. of patients i.e. 80 % were of moderately nourished status. Total of 30 patients, the weakness feature was seen in maximum no. of 96.67 % patients, Dyspnoea and Pallor in 83.33 % patients each, Fatigue in 76.67 % patients, Vertigo in 73.33 %, Loss of Appetite in 70 % patients and brittle nails in 16.67 % patients. Ankle oedema and smooth tongue was not found in any of the registered patients. Before the start of treatment, Maximum no 50 % patients were having haemoglobin in the range of 8-10 gm/dl and After the completion of treatment, Maximum no. 70 % patients were having haemoglobin in the range of 10-12 gm/dl.

Subjective parameters (Intragroup comparison {BT&AT} as a Wilcoxan paired sign ranked Test) table no :1

Variables	Gr.	Mean B.T.	Mean A.T.	Mean Dif.	Mean %	No.	S.D.	S.E.	t	p	S
Palpitation	A	2.43	0.93	1.50	61.76%	14	0.52	0.14	10.82	< 0.001	HS
	B	1.75	0.67	1.08	61.90%	12	0.29	0.08	13.00	< 0.001	HS
Dyspnoea	A	1.33	0.33	1.00	75.00%	12	0.00	0.00	1.00	<0.1	IS
	B	1.17	0.33	0.83	71.43%	12	0.39	0.11	7.42	< 0.001	HS
Fatigue	A	1.69	0.85	0.85	50.00%	13	0.69	0.19	4.43	< 0.001	HS
	B	1.20	0.60	0.60	50.00%	10	0.52	0.16	3.67	< 0.010	S
Vertigo	A	1.00	0.36	0.64	63.64%	11	0.50	0.15	4.18	< 0.005	HS
	B	1.09	0.45	0.64	58.33%	11	0.50	0.15	4.18	< 0.005	HS
Weakness	A	1.47	0.80	0.67	45.45%	15	0.62	0.16	4.18	< 0.001	HS
	B	1.36	0.50	0.86	63.16%	14	0.36	0.10	8.83	< 0.001	HS
Pallor	A	1.23	0.46	0.77	62.50%	13	0.60	0.17	4.63	< 0.001	HS
	B	1.33	0.50	0.83	62.50%	12	0.58	0.17	5.00	< 0.001	HS
Brittle Nails	A	1.33	1.00	0.33	25.00%	3	0.58	0.33	1.00	>0.1	IS
	B	1.00	0.50	0.50	50.00%	2	0.71	0.50	1.00	> 0.1	IS
Loss of appetite	A	1.00	0.33	0.67	66.67%	15	0.62	0.16	4.18	< 0.001	HS
	B	1.00	0.44	0.56	55.56%	9	0.53	0.18	3.16	< 0.025	HS

Objective parameters (Intergroup comparison{BT&AT} as a Paired T test. Table no :2

Variables	Gr.	Mean B.T	Mean A.T.	Mean Diff.	Mean %	No.	S.D.	S.E.	t	p	S
Hb gm%	A	9.39	11.60	2.21	23.58%	15	1.3	0.3	6.4	<	H

							3	4	4	0.001	S
	B	9.66	11.50	1.84	19.05%	15	1.30	0.33	5.50	< 0.001	HS
TRBC	A	3.62	4.18	0.57	15.66%	15	0.47	0.12	4.68	< 0.001	HS
	B	3.58	4.23	0.65	18.00%	15	0.65	0.17	3.84	< 0.005	HS
ESR	A	26.53	13.93	12.60	47.49%	15	17.5	4.54	2.78	< 0.025	HS
	B	21.80	11.00	10.80	49.54%	15	23.3	6.02	1.79	< 0.1	HS
PCV	A	28.42	33.75	5.33	18.74%	15	4.42	1.14	4.66	< 0.001	HS
	B	28.47	33.57	5.09	17.89%	15	5.32	1.37	3.71	< 0.005	HS
MCV	A	76.25	81.11	-4.87	-6.38%	15	10.8	2.81	1.73	> 0.1	IS
	B	83.13	79.57	3.56	4.28%	15	13.6	3.53	1.01	> 0.1	IS
MCH	A	26.73	30.43	3.70	13.84%	15	5.54	1.43	2.59	< 0.025	S
	B	28.12	28.13	0.01	0.02%	15	5.02	1.30	0.01	> 0.1	IS
MCHC	A	32.13	34.74	2.61	8.13%	15	3.03	0.78	3.34	< 0.005	HS
	B	34.04	33.88	0.16	0.47%	15	1.65	0.43	0.38	> 0.1	IS
Serum Iron	A	75.15	98.40	23.25	30.94%	15	6.37	1.65	14.1	< 0.001	HS
	B	73.34	114.12	40.78	55.60%	15	10.2	2.65	15.4	> 0.1	IS
TIBC	A	393.58	333.57	60.01	15.25%	15	9.97	2.57	23.3	< 0.001	HS
	B	391.17	306.39	84.77	21.67%	15	32.3	8.34	10.1	< 0.001	HS

Objective parameters intergroup comparison as a Unpaired T Test. Table no 3

Variables	Gr.	Mean Diff.	S.D.	S.E.	n	t	p	S
Hb gm%	A	0.37	1.33	0.34	28	0.77	<0.44	I.S.
	B		1.33	0.34				
TRBC	A	0.07	0.47	0.12	28	0.38	<0.70	I.S.

	B		0.65	0.17				
ESR	A	1.8	17.57	4.54	28	0.23	< 0.81	I.S.
	B		23.32	6.02				
PCV	A	0.23	4.42	1.14	28	0.13	<0.89	I.S.
	B		5.32	1.37				
MCV	A	8.42	10.87	2.81	28	1.89	< 0.07	I.S.
	B		13.67	3.53				
MCH	A	3.69	5.54	1.43	28	1.91	< 0.06	I.S.
	B		5.02	1.30				
MCHC	A	2.77	3.03	0.78	28	3.11	< 0.004	H.S.
	B		1.65	0.43				
Serum Iron	A	17.52	6.37	1.65	28	5.62	< 0.0001	H.S.
	B		10.26	2.65				
TIBC	A	24.76	9.97	2.57	28	2.83	< 0.008	H.S.
	B		32.32	8.34				

Subjective parameters assessment (Intergroup Comparison) as a Mann- Whitney Test

Table no :4

Variables	Group	Mean Dif.	S.D.	S.E	P	S
Palpitation	Group A	1.50	0.52	0.14	< 0.0094	H.S.
	Group B	1.08	0.29	0.08		
Dyspnoea	Group A	1.00	0.00	0.00	< 0.21	I.S.
	Group B	0.83	0.39	0.11		
Fatigue	Group A	0.85	0.69	0.19	< 0.096	I.S.
	Group B	0.60	0.52	0.16		
Vertigo	Group A	0.64	0.50	0.15	<0.49	I.S.
	Group B	0.64	0.50	0.15		
Weakness	Group A	0.67	0.62	0.16	< 0.21	I.S.
	Group B	0.86	0.36	0.10		
Pallor	Group A	0.77	0.60	0.17	< 0.49	I.S.
	Group B	0.83	0.58	0.17		
Brittle Nails	Group A	0.33	0.58	0.33	< 0.48	I.S.
	Group B	0.50	0.71	0.50		
Loss of appe-tite	Group A	0.67	0.62	0.16	< 0.064	I.S.
	Group B	0.56	0.53	0.18		

DISCUSSION

Pandu Roga is *Pitta pradhana Trido-shaja vyadhi*, involving *Rasavaha srotasa &*

Raktavaha Srotasa. Pitta Dosha is responsible for the normal color of the body but when it gets vitiated as happens in *Pandu Roga*; there is loss of complexion or *Panduta (*pale white*)* occurs.

Observations show that the onset is common in younger middle age groups. *Pandu* is more common in adolescents due to the intake of iron deficient diet. The *Pandu Roga* is more prevalent in malnourished males and females. In statistical analysis of clinical features of *Pandu Roga* in Group-A treatment with *Nisha Lauha and Phalatrikadi Kwath*, the features like palpitation, Fatigue, Vertigo, Weakness, Pallor, Loss of appetite showed highly significant improvement (<0.001). Dyspnoea and brittle nails showed insignificant improvement. In Group-B, Palpitation, Dyspnoea, Vertigo, Weakness, Pallor, Loss of appetite showed highly significant improvement (<0.001). Significant improvement has been observed in *Fatigue* with P-value <0.01. Brittle nails have shown insignificant improvement. Highly significant improvement was observed in hemoglobin level after sixty days treatment in both groups A and B. The intergroup comparison showed equal results in both the groups which are statistically insignificant. In case of ESR, PCV, MCH, MCHC, TRBC, S. Iron, TIBC in both groups statistically highly significant results observed in both the groups (<0.001) .

As per the observations and results found in the clinical study, both the trial drugs are effective to manage *Pandu Roga* compared to *ferrous sulphate.* The regular use of *Amla* can strengthen digestion, absorption and assimilation of food. *Amalaki* is the richest source of Vit-C. It is helpful in promoting the absorption of food and elemental iron in the body. It is also helpful in maintaining the proper peristaltic movements in the body. It improves assimilation of iron for healthy blood. Studies have shown it beneficial in increasing RBC count & haematocrit ferrous sulphate is an established drug in Iron Deficiency Anaemia which has been further consolidated in present clinical study showing statistically highly significant results.

Analysis of the Pharmacodynamic properties of the *Nisha Lauha and Phalatrikadi Kwath* the *Rasa* present in the individual drug reveals that maximum have *Katu* and *Tikta rasa*. Its *Agnideepana* function increases the metabolism and reduces the formation of *Ama* (indigestive food juice) by virtue of *Tikta* and *Katu rasa*. *Amalaki* is best *Rasayana* and *Pitta shamaka*. *Amalaki*, one of the content of *Nisha Lauha and Phalatrikadi Kwath*, it contains high amount of Vitamin C, which reduces ferric iron to ferrous iron which remains soluble even at neutral pH and is better absorbed. *Amalaki* has a good effect on circulatory system and is of great importance to heart. It keeps check on all the toxins in the body circulating in blood; it possesses *tikta rasa*. It helps in producing good quality red blood cells.

Curcumin (Haridra) extracts of turmeric root reduced secretion of acid from the stomach and protected against injuries such as inflammation along the stomach (gastritis) or intestinal walls and ulcers from certain medications, stress, or alcohol. The *Rasayana* drug (*Amalaki*, *Pippali*) improves the quality of *rasa dhatu* thereby entire status of the body. This improves the body immune system.

Lauha bhasma one is a powerful haematinic. It stimulates the appetite and has a general vitalizing effect. It is readily assimilated in the body. *Lauha bhasma* is the choicest remedy for anemia. It also possessed a rejuvenating property. In *Nisha Lauha*, the iron is in natural form. The herbal ingredients of the above drugs increase the bioavailability of natural form of iron and enhance iron absorption thus increasing the acceptability of iron to the body. Both drugs *Nisha Lauha and Phalatri-*

kadi Kwath and *Ferrous sulphate* can be prescribed confidently in the treatment of *Pandu Roga*.

CONCLUSIONS:

- *Pandu* is a *Tridoshaj vyadhi* with *pitta* as the main *dosha*.
- Drugs having the properties like *deepan, pachana ,balya* and *rasayan* are useful in the treatment of *Pandu*.
- Pitta dosha dominant Prakriti patients are more to develop Pandu.
- Females are more affected than males.
- No age group is free from Pandu.
- Both quality and quantity of diet play an important role in the manifestation of Pandu.
- *Nisha lauha* and *Phaltrikadi Kwath* both provided better results in improving signs and symptoms. Both drugs found to have role in increasing the Hb% level.

RECOMMENDATIONS:

- The study should be carried out in large no of patients to evaluate and analyse the results.
- The drug should be administered done for longer duration (3-4 months) for better results.
- As *Pandu Roga* is a chronic disease follow up should be kept for longer duration.
- More objective parameters in the form of Laboratory investigations should be adopted for proper the diagnosis of Pandu.
- Pandu being a demographic disorder, efforts should be made to overcome it as it effects work performance in adults, reduces learning ability in adolescents with 8-10% decrease in Intelligence Quotient (I.Q.)
- Safety profile of drugs needs to be extensively studied and documented for more validation and authentication of clinical research study.
- Budgetary allocations should be enhanced.

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