

**A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF  
“NISHALAUHA WITH FERROUS SULPHATE” IN THE MANAGMENT OF PANDU  
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**ABSTRACT**

**Introduction:** Anaemia is the most prevalent disorder in the world. Anaemia refers to a state in which the level of haemoglobin in the blood is below the normal range for corresponding age and sex. *Pandu Roga* as disease may very well compare with Anaemia. In our classical texts, the description of Pandu is available in three forms; i.e. Pandu as a disease, Pandu as a complication and Pandu as a sign of certain diseases. **Aim:** To evaluate and compare the effect of *Nishalauha* and Ferrous Sulphate on *Pandu* (IDA) **Material and Methods:** The study was conducted in 40 clinically diagnosed patients of anaemia. There were two trial groups with 20 Patients in each trial group. Group I- In this group each subject was given 500 mg tab of *Nishalauha* once daily. Group II- In this group each subject was given 200 mg tab of Ferrous Sulphate once daily. Total duration of the trial was 30 days. Follow up was done after every 15 days of commencement of therapy. Among 40 registered patients, 36 patients had completed the treatment and 4 patients discontinued the treatment. “Paired t-test” was carried out for various objective parameters within the group and “unpaired t-test” was carried out between the groups. **Result:** At the end of study, drug has shown beneficial effect in the patients of anaemia. The trial drug *Nishalauha* is effective to improve clinical features and hematological parameters significantly. The medicine is effective to increase the hemoglobin level 1.58 g/dL (9.79- 11.37g/dL, P < 0.001) in 30 days. No adverse effect of the trial drug was observed during the study. **Conclusion:** The results suggest that *Nishalauha* is significantly effective in the management of IDA.

**KEYWORDS:** Anaemia, *Nishalauha*, *Pandu*.**INTRODUCTION**

Since the time immemorial humans consistently strive for their good health and till date the process is going on.

Ayurveda being the science of life is being practiced since the ancient Vedic times. The two main objectives of Ayurveda are-

प्रयोजनं चास्य स्वस्थस्य स्वास्थ्यरक्षणमातुरस्य विकारप्रशमनं च ॥ (च०सू० 30/26)

1. To maintain the health of the person (i.e Swastha Rakshan).
2. If got disease then establish the healthy and homeostatic atmosphere (i.e. Vikaraprashamanam).

Acharya Sushruta defines Swasthya as

समदोषः समग्निश्च समघातमलकियः प्रसन्नात्मेनिदयमनाः स्वस्थ इत्यभिधीयते ॥  
(स०सू० 15/48)

i.e. Swasthya is a equilibrium state with normal functioning of dosha, agni, Dhatu, mala along with Prasanna Atma, Indriyas and Mana.

विकारो धातुवैषम्यं साम्यं प्रकतिरुच्यते। (च०सू० 9/4)

And the reason behind the disease to emerge is Dhatu derangement. i.e, the reason for disease to occur is Dhatu Vaishamyata.

*Pandu Roga* is one among the diseases which occurs due to Dhatu Vaishamyata. In our classical texts, the description of *Pandu* is available in three forms; i.e., *Pandu* as a disease, *Pandu* as a complication and *Pandu* as a sign of certain diseases. Considering *Panduta* (pallor) as the predominant sign, the disease is termed as *Pandu roga* and also has been described like- ‘Ketki Dhooli Sannibham’.

Anaemia refers to a state in which the level of haemoglobin in the blood is below the normal range for corresponding age and sex. Anaemia is the most prevalent disorder in the world.

Globally, anaemia affects 1.62 billion people which corresponds to 24.8 % of the population. In India, Anaemia affects approximately 50% of the population. The problem is more prevalent in women.

The manifestation of clinical features of Anaemia depends upon the etiopathological process, the severity of anaemia and age of the patient. It is characterized by pallor, fatigue, breathlessness and reduced exercise capacity, that is why may compare with the Pandu Roga which possesses Lakshanas like Sadana (malaise), Shrama (exhaustion), Shwasa (dyspnoea), Hata Prabha (loss of lustre), Aarohana Aayasaihi visheshaha (feels breathlessness while climbing steps or going uphill) etc.

Nishalauha is an Ayurvedic herbo-mineral formulation quoted in *Bhaishajya Ratnavali* for the treatment of Pandu Roga. With the aim that herbomineral medicines may be effective to manage IDA without any side effects, the present study was carried out to know the efficacy of an Ayurvedic herbomineral compound Nishalauha.

**Aim:** To evaluate and compare the effect of *Nishalauha* and Ferrous Sulphate on *Pandu* (IDA).

To study the other associated effect of the trial drugs if any.

## MATERIAL AND METHODS

40 patients with anemia were included in the study. Patients who meet the inclusion criteria were enrolled for the study. The patients presenting with the sign and symptoms of Pandu Roga has been selected from OPD and IPD Department of Rog Nidan Evum Vikriti Vigyan of R.G.G.P.G. Ayurvedic College and Hospital Paprola, Distt.Kangra (H.P.) Among 40 registered patients, 36 patients had completed the treatment and 4 patients discontinued the treatment due to their personal reasons. Approval for clinical study was taken from Institution Ethics Committee of R.G.G.P.G. Ayu. College & Hospital, Paprola vide letter no.

Ayu/IEC/2019/1240. Written and informed consent of

patients was taken from all the patients before inclusion in the trial.

### Criteria for the selection of the patients:

#### Inclusion criteria

- Patients having Hemoglobin level 8 to 11 gm%.
- Patients of either sex between 12 to 60 years.
- Blood picture presenting either microcytic hypochromic or normocytic hypochromic anaemia.
- In pregnancy after 1<sup>st</sup> trimester.

#### Exclusion criteria

- Patients having Hemoglobin level less than 8 gm%
- Anaemia resulting from acute or chronic blood loss.
- Patients showing allergy to the trial drug.
- Sideroblastic anaemia, Thalassemia major and minor.
- Anaemia in association with other systemic disorders which interferes with the prognosis and treatment of the case.

#### Discontinuation Criteria

- Failure to turn up for follow-up.
- Those not following advice.
- If the condition of person on trial deteriorated during trial he/she shall be excluded from study.

#### Selection of the drug

Nishalauha is an Ayurvedic herbo-mineral formulation quoted in *Bhaishajya Ratnavali* for the treatment of *Pandu roga*. Ferrous sulphate is commonly used for IDA at government health care facilities.

#### Preparation of Drug

Individual ingredient of trial drug was identified by experts of Dravyaguna department of college and trial drug was prepared in Charak Pharmacy of the institute under supervision of pharmacy experts. It was prepared as per Good Manufacturing Practice norms. Entire drug prepared in a single lot. While ferrous sulfate for group II was procured from PHC.

#### Contents of Nishalauha

लौहचूर्णं निशायुग्मं त्रिफला रोहिणीयुतम् ।  
प्रलिहयात् मधुसर्पिभ्यां कामलापाण्डु शान्तये ॥  
(भै.र.12/29)

S. No.	Name	Botanical Name	Family	Part used	Quantity
1.	<i>Haridra</i>	<i>Curcuma longa</i>	Zingiberaceae	Rhizome	1 Part
2.	<i>Daruharidra</i>	<i>Berberis aristata</i>	Zingiberaceae	Root	1 Part
3.	<i>Haritaki</i>	<i>Terminalia chebula</i>	Combretaceae	Fruit (Pericarp)	1 Part
4.	<i>Bibhitaki</i>	<i>Terminalia bellirica</i>	Combretaceae	Fruit (Pericarp)	1 Part
5.	<i>Amalaki</i>	<i>Emblica officinalis</i>	Euphorbiaceae	Fruit (Pericarp)	1 Part
6.	<i>Kutki</i>	<i>Picrorhiza kurroa</i>	Scrophulariaceae	Rhizome	1 Part
7.	<i>Lauha bhasma</i>				6 Part

**Analytic study of trial drug**

The trial drug sample was subjected to various physicochemical analytical tests to evaluate the standards of drug. Analytical test reports of the trial drug *Nishalauha* are as follows-

**Appearance-** Tablet shaped

**Color-** Blackish

**Odor-** Characteristics

**Taste-** Bitter and Astringent

**pH-** 3.96

**Total solid-** 95.26%

**Total ash-** 39.70

**Acid soluble ash-** 21.68%

**Water soluble extract-** 15.96%

**Date of expiry-** five year from the Date of manufacturing  
The sample exhibited positive test for iron.

**Schedule for the treatment**

There were two trial groups with 20 patients in each trial group.

Group 1- In this group each subject was given 500 mg tab of *Nishalauha* once daily. Group II- In this group each subject was given 200 mg tab of Ferrous Sulphate once daily.

Route- Oral

Frequency of Administration- OD Duration of Administration- 30 days Follow up- After 15 days  
Anupana- Go-ghrita and Madhu

**Laboratory investigation**

Complete Hemogram: haemoglobin, Red Blood Cell (RBC) count, Total Leucocyte Count (TLC), Differential Leucocyte Count (DLC), Erythrocyte Sedimentation Rate (ESR), Packed Cell Volume (PCV), Mean Corpuscular Volume (MCV), Mean Corpuscular Haemoglobin (MCH), Mean Corpuscular Haemoglobin Concentration (MCHC), Platelet Count and Peripheral Blood Film (PBF).

Blood Biochemistry: Serum ferritin, Blood sugar, Blood urea, Serum creatinine, Serum glutamic oxaloacetic transaminase (SGOT), Serum glutamic pyruvic transaminase (SGPT), Total serum bilirubin (TSB) and Direct serum bilirubin (DSB).

Urine: routine and microscopic examination of the urine was done for the presence of any blood.

These investigations were done in attached pathology laboratory of the institute in all the patients before the treatment and after completion of the treatment.

**Criteria of Assessment**

Assessment was done by considering the change in both the subjective and objective parameters before the treatment and after the treatment. The following parameters were mainly adopted for assessing the

response of the treatment.

**A. Subjective parameters**

- Signs and symptoms of *Pandu roga* i.e., *Daurbalyata* (weakness), *Hridspandanam* (palpitation), *Bharam* (giddiness), *Rukshata* (dryness), *Shawas* (dyspnea), *Hatanal* (loss of appetite), *Sharam* (fatigue), *Gatrashoola* (bodyache), *Karana Kshweda* (Tinnitus), *Twaka Panduta* (pallor).
- Assessment of *Sharirik* and *Manshik Prakriti*, *Agni Bala*, *Deha Bala*, *Sattwa Bala*.
- Scoring of health and quality of life.

**B. Objective parameters**

- ✓ Hb%, Serum Ferritin

**Criteria For Over All Assessment:** The total effect of the therapy was assessed considering the following criteria.

- Markedly Improvement: (76-100%) relief in the signs & symptoms.
- Moderately Improvement: (51-75%) relief in the signs & symptoms.
- Mild Improvement: (26-50%) relief in the signs & symptoms.
- Unchanged: < 25% relief in the signs & symptoms.

**Statistical analysis:** "Paired t-test" was carried out for various objective parameters within the group and "unpaired t-test" was carried out between the groups.

**Observation**

Total 40 patients of *Pandu roga* (IDA) were registered in the clinical study and randomly divided in two groups viz. Group A and Group B. Out of 40 cases, 36 patients completed the treatment course while 4 patients dropped out. In Group A 20 patients were registered and 18 patients completed the treatment. In Group B 20 patients were registered and 18 patients completed the treatment.

In this study, maximum patients 26 (65%) were from age group of 21-30 years, 8 (20%) were in age group of 31-40 years and 6 (15%) were in age group of 16- 20. 38 (95%) patients were female, 2 (5%) patients were male. Considering religion, 39 (97.5%) patients were Hindu and 1 (2.5%) was Christian. Maximum patients i.e., 40 (100%) belong to rural area. In this study, 26 (65%) patients were married, 34 (85%) patients were in middle income group, and 30 (75%) of people were having vegetarian dietary habits.

Maximum number of patient 16 (40%) were of *Vat-Pittaja Prakriti*, 11 (27.5%) patients were of *Pitta-Vataja*. Regarding *Manasika Prakriti* 27 (67.5%) of Patients were of *Rajasika Prakriti*, and 25 (62.5%) of the patients had *Manda agni*.

It was observed that *Sharam* was observed in 39 (97.5%) patients. *Daurbalya* was present in 37(92.5%) patients. While 36 (90%) patients presented with complaint of

Gatarshool.

Sramajanya Shawas was observed in 29 (72.5%) patients. 18 (45%) patients complained of Hatanal and Twakpanduta. Rukshata was observed in 14 (35%). Bharma was observed in 13 (32.5%). Hridyaspandan was observed in 6 (15%). Only 2 (10%) patients complained of 4(10%).

## RESULT

*Nishalauha* was found statistically highly significant ( $P < 0.0001$ ) in all major complaints i.e., Daurbalyata (88.88%), Sramajanya shawas (94.12%), Sharam (97.64%), Gatarshool (82.74%), Twakpanduta (74.91%).

### Effect of therapy on the Symptoms in Group -1 NISHA LAUHA patients (paired t test) No of Patients: 18

Symptoms	Mean		% relief		SD±	SE±	't'	P
	BT	AT	Diff.	%age				
<i>Daurbalyata</i>	2.5	0.278	2.222	88.88%	0.943	0.222	10	<0.001
<i>Hridyaspandan</i>	0.5	0.111	0.389	77.8%	0.778	0.183	2.122	0.049
<i>Bhrama</i>	0.722	0.00	0.722	100%	1.018	0.240	3.010	0.008
<i>Rukshata</i>	0.500	0.389	0.111	22.2%	0.323	0.0762	1.458	0.163
<i>Sramajanya shawas</i>	1.889	0.111	1.778	94.12%	1.003	0.236	7.518	<0.001
<i>Hatanal</i>	0.667	0.00	0.677	100%	0.840	0.198	3.367	0.004
<i>Sharam</i>	2.333	0.0556	2.278	97.64%	0.826	0.195	11.693	<0.001
<i>Gatarshool</i>	1.611	0.278	1.333	82.74%	0.767	0.181	7.376	<0.001
<i>Karanshavedha</i>	0.167	0.00	0.167	100%	0.383	0.0904	1.844	0.083
<i>Twakpanduta</i>	1.111	0.278	0.833	75%	0.786	0.185	4.499	<0.001

### Effect of therapy on the Symptoms in Group -2 Ferrous sulphate patients (paired t test) No of Patients: 18

Symptoms	Mean		% relief		SD±	SE±	't'	P
	BT	AT	Diff.	%age				
<i>Daurbalyata</i>	1.833	0.889	0.944	51.5%	0.802	0.189	4.994	<0.001
<i>Hridyaspandan</i>	0.111	0.0556	0.0556	50%	0.236	0.0556	1.00	0.331
<i>Bharma</i>	0.278	0.0556	0.222	79.85%	0.548	0.129	1.719	0.104
<i>Rukshata</i>	0.333	0.333	0.00	0%	0.00	0.00	0.00	1.00
<i>Sramajanya shawas</i>	1.056	0.444	0.611	57.85%	0.778	0.183	3.335	0.004
<i>Hatanal</i>	0.889	0.389	0.500	56.24%	0.786	0.185	2.699	0.015
<i>Sharam</i>	2.222	0.889	1.333	59.99%	0.485	0.114	11.662	<0.001
<i>Gatarshool</i>	1.611	0.667	0.944	58.59%	0.725	0.171	5.524	<0.001
<i>Karanshavedha</i>	0.0556	0.0556	0.00	0%	0.00	0.00	0.00	1.00
<i>Twakpanduta</i>	0.222	0.0556	0.167	75%	0.383	0.0904	1.844	0.083

### Inter Group Comparison

Symptoms	% Relief			't'	P	Result
	Group-I	Group-II	Diff %age			
<i>Daurbalyata</i>	88.88%	51.5%	37.38%	4.379	<0.001	H.S.
<i>Hridyaspandan</i>	77.8%	50%	27.8%	1.741	0.091	H.S.
<i>Bharma</i>	100%	79.85%	20.15%	1.844	0.083	Significant
<i>Rukshata</i>	22.2%	00%	22.2%	1.458	0.154	N.S.
<i>Sramajanya shawas</i>	94.12%	57.85%	36.27 %	4.229	<0.001	H.S.
<i>Hatanal</i>	100%	56.24%	43.76%	0.615	0.543	N.S.
<i>Sharam</i>	97.64%	59.99%	37.65%	4.181	<0.001	H.S.
<i>Gatarshool</i>	82.74%	58.59%	24.15%	1.563	0.127	N.S.
<i>Karanshavedha</i>	100%	0%	100%	1.844	0.074	H.S.
<i>Twakpanduta</i>	75%	75%	00%	3.234	0.003	H.S.

Inter group comparison of effect of therapy on Hb observed after the completion of therapy was statistically non-significant ( $p = 0.862$ ). The result revealed that therapy given in Group- I showed better result with higher increase in Hb i.e. 16.12 % as compared to Group- II i.e. 15.90%.

**Intergroup comparison of effect of therapy on Hb**

Group	Mean Diff.	% age relief	SD	T	P
I	1.578	16.12	1.057	0.176	0.862
II	1.633	15.90	0.827		

Inter group comparison of effect of therapy on S. Ferritin observed after the completion of therapy was statistically significant (p= 0.099). The result revealed that therapy

given in Group- I showed better result with higher increase in S. Ferritin i.e.92.35 % as compared to Group-II i.e.59.18%.

**Intergroup comparison of effect of therapy on S. FERRITIN**

Group	Mean Diff.	% age relief	SD	T	P
I	48.434	92.35	20.713	1.696	0.099
II	36.772	59.18	20.54		

**Comparison of Overall Effect of Therapy in Both Groups**

Results	Group I (n=18)		Group II(n=18)	
	No. of Patients	%age	No. of Patients	%age
Markedly Improved (76%-100%)	15	83.33%	1	0.05%
Moderately Improved (51-75%)	2	11.11%	7	38.88%
Mildly Improved (25-50%)	1	0.05%	10	55.55%
No improvement (<25%)	0	0	0	0

**DISCUSSION**

*Pandu Roga* can be clinically correlated with Anaemia. As in both *Pandu Roga* and Anaemia there are similar sign and symptoms such as pallor, easy fatigability, decrease appetite, generalized body aches.

In the present Research work based on facts, observations and result of drug and clinical studies, the following conclusion can be drawn:

Anaemia is a condition that affects children and reproductive age women and can-do major health consequences. Anaemia remains a major health problem, especially among females in less developed countries.

In this study, maximum number of patients i.e. 65% belongs to the age group of 21-30years. (Yovan period) which is the period of Pittaj predominance so it makes them prone to Anaemia. Maximum numbers of patients i.e., 95 % were females. Thus, it can be said that *Pandu Roga* is more prevalent in females, Probable reason behind this observation may be loss of blood in menstruation, more inclination towards junk food spicy food, pickles, Amla Rasa which are Pitta Vardhaka. This makes them more prone to *Pandu Roga*. Higher incidence was found in housewives (42.5%) as may be due to family stress and family work load. In all these conditions ingested food not assimilate or absorb properly and may leads to Anaemia.

In the present study maximum number of patients registered belonged to middle class (85%) of society. The reason for acquiring anemia in middle class community may be due to excessive indulgence of fast foods, dairy products (Which reduce iron absorption) and habit of skipping breakfast and meal due their busy life

style. Patients from poor and lower middle class can't afford expensive food, vegetables as well as medicines for this disease, Moreover, poor people are unable to afford the proper diet and hence they suffer from this disease.

Agni wise distribution of patients reveals that maximum patients (62.5%) were having *Mridu Agni*. This observation is of very much importance as according to Ayurvedic fundamentals "*Rogasarveapi mandagnyou*" i.e. root cause of every disease is *Mandagni*. *Mandagni* results in to *Ama* production and improper *Rasa dhatu* formation which is the initial step in development of all diseases.

**Probable mode of action**

The mode of action of Ayurvedic drugs is very unique as compared to modern medicine system. The action of every drug is determined by the dominant pharmacodynamic factors in that particular drug and that may be *Rasa*, *Guna*, *Veerya*, *Vipaka* and *Prabhava*.

**Tikta Rasa** does *Pittashaman*, *Kashya Rasa* absorbs the *Kapha*, *Katu Rasa* clears the obstruction of *Kapha*.

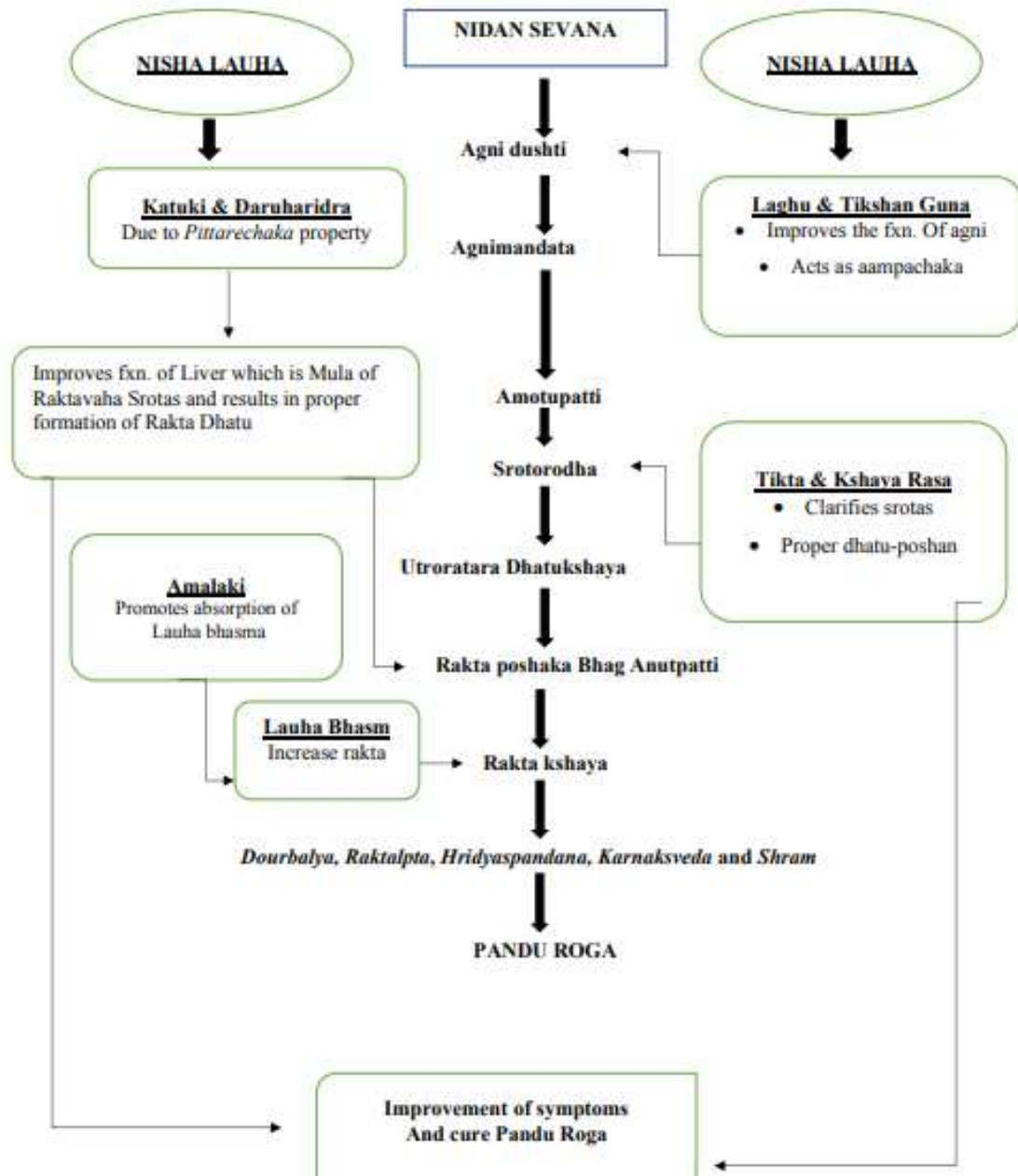
**Due to laghu and ruksha guna**, this medicine possesses the *Lekhan* property that brings lightness and clears obstruction by removing vitiated *Kapha*. That's the reason by which the patient got relief in symptoms like *Gatarshool*, *Sharam*.

**Ushana Veerya** has *Deepan Panchana* properties which metabolise *Samapitta* that cures symptoms like *Hatanal*, *Daurbalyata*, *Tawakpanduta*. It also brings lightness to body by *Aampachan*. *Katu Vipaka* is *Agnivardhak* and *Srothoshodak* which cures the symptoms like *Daurbhalya*

and Hatanal.

Maximum contents of Nisha Lauha are having Kaphapittshamak property. In the pathogenesis of Pandu, Pitta and Kapha are mainly involved. As we know Rakta Dhatu is the Dushya of Pitta Dosha and according to Doshadushya Ashrayashrayibhava, aggravation of Pitta

dosha leads to Rakta Dhatu Pradushna (vitiation). Due to Pittashamaka property of the trial drug Rakta Dhatu don't get vitiated and there is no further progression of the disease occurs. So, we can say that due to Kapha and Pitta Shamaka property Nishalauha helps in curing Pandu.



Further, the activity of Nishalauha gets potentiated as it is to be administered with unequal amount of Go Ghrita and Madhu (Honey) as an adjuvant of which have therapeutic attributes better absorption of the drug.

## CONCLUSION

Nishalauha has been subjected to a clinical study on patients suffering from IDA. It contains iron (*Lauha*

*Bhasma*) and herbal ingredients (*Triphala, Katuki, Haridra* and *Daruharidra*). Herbal ingredients present in the trial drug may increase the bioavailability of iron. Hematinic action of Nishalauha may be due to the presence of iron contents of good bioavailability. The present clinical study clearly indicates that the herbomineral formulation Nishalauha is an effective, well-tolerated, and clinically safe formulation for the management of IDA in patients.

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