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RESEARCH ARTICLE

Clinical Efficacy and Safety of *Punarnavadi Mandura* and *Dadimadi Ghrita* in the Management of Iron Deficiency Anemia: A Prospective Open-label Multicenter Study

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ABSTRACT

Background: Iron deficiency anemia is one of the most prevalent types of nutritional disorder in the world. Its etiology is multifaceted and it generally results when the iron demands of the body are not met by iron absorption. Iron deficiency anemia can be symptomatically compared with *Pandu Roga* in Ayurveda.

Aims and objectives: To evaluate the efficacy and safety of *Punarnavadi Mandura* and *Dadimadi Ghrita* in patients suffering from iron deficiency anemia.

Materials and methods: A prospective, open-label multicenter study was carried out at three peripheral centers of the Central Council for Research in Ayurvedic Sciences. One hundred three patients satisfying the selection criteria were enrolled from the outpatient department of these centers and were administered *Punarnavadi Mandura* (500 mg) and *Dadimadi Ghrita* (10 gm) twice daily before food with lukewarm water for 12 weeks. Follow-up was done finally after 2 weeks without medication. However, data of 90 patients were used for analysis. Hematological parameters, viz., hemoglobin, mean corpuscular hemoglobin concentration, mean corpuscular volume, packed cell volume, total iron-binding capacity, serum ferritin, and serum iron, were assessed at baseline, 42nd day, and at the end of the treatment period of 12 weeks (i.e., 84th day). Paired sample t-test was used to compare mean change from baseline with the 84th day. A p-value of <0.05 was considered significant.

Results: At the end of 12 weeks, compared with baseline, statistically significant increase was observed in mean serum iron level (p-value = 0.005). However, mean change from baseline to 84th day in hemoglobin level (p-value = 0.325) was not significant. A significant improvement in symptoms of anemia, such as weakness, fatigue, dizziness, and headache, was also seen. The treatment was found to be safe and effective in the patients with iron deficiency anemia as all the safety parameters were within the stipulated range. No adverse drug reaction or adverse events were reported during the trial period.

Conclusion: *Punarnavadi Mandura* and *Dadimadi Ghrita* administered together in the above-mentioned dose were found effective and safe in patients suffering from iron deficiency anemia.

Keywords: Dadimadi Ghrita, Iron deficiency anemia, Pandu, Punarnavadi Mandura, Serum ferritin.

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INTRODUCTION

Iron deficiency anemia is the most common type of nutritional disorder in the world. The prevalence of anemia in India among women and children is highest in the world. In India, the prevalence of anemia is high because of[1]:

- Low dietary intake, specifically poor iron (less than 20 mg/day) and folic acid intake (less than 70 mg/day);
- Poor bioavailability of iron (3–4% only) in phytate fiber-rich vegetarian diet; and
- Chronic blood loss due to infection, such as malaria, and parasitic infestations, such as hookworm.

Anemia is a state of reduced hemoglobin in the body. It is associated with various signs and symptoms like breathlessness, pallor, fatigue, weakness, etc. Patients report fatigue and exercise-associated dyspnea besides paleness of the skin. As per Ayurveda, we may correlate this with *Pandu* based on signs and symptoms of the disease.[2]

Iron is present in the body abundantly in the form of hemoglobin and in the form of ferritin that helps in erythropoiesis, besides other forms of proteins that have iron in them. A serum ferritin level of 15 µg/L or less is diagnostic of iron deficiency. Red blood cell (RBC) size,

color, mean corpuscular volume, and packed cell volume are the other parameters that can be assessed to diagnose and evaluate the effect of treatment.[3]

Pandu in Ayurveda is characterized with a marked vitiation of *Pitta* along with the other doshas. Due to specific *nidana* (etiological factors), vitiated *vata* displaces *Pitta* which vitiate further *Kapha, rasa, rakta*, and *mamsa*, gets lodged in between *twak* and *mamsa* resulting in yellowish or greenish discoloration of the skin. The prodromal symptoms include palpitation, dryness of the skin, absence of sweating, and tiredness of the body which are *vata* predominant. When the disease manifests properly, the symptoms exhibited include low digestive activity and anorexia which reflect the impairment of *agni* due to vitiation of *Pitta*. The symptoms like tinnitus, tiredness even after small exertion, body ache, low voice, brittle hair, etc., can be attributed to *Vata* and the symptoms like swelling of eye sockets, drowsiness, frequent spitting, etc., due to *Kapha*. Therefore, management of the disease should be aimed at correcting the vitiation of *Tridosha* and improving the *Agni*.

Punarnavadi Mandura was selected as it is an iron preparation being used since years to treat *Pandu roga* and as *Rukshata* is one of the four prodromal symptoms of *Pandu*, *Dadimadi Ghrita* was selected for *Abhyantar Snehana*. Further, *Dadimadi Ghrita* was also used to counter the *Khaributata* of body tissue or *Dhatus*. *Dadimadi Ghrita* is also responsible for *Agni deepan* and thus was used so that *Punarnavadi Mandura* can be better absorbed.

OBJECTIVES

To evaluate the efficacy and safety of two classical Ayurvedic formulations *Punarnavadi Mandura* and *Dadimadi Ghrita* in patients with iron deficiency anemia.

MATERIALS AND METHODS

Study Design

The study was a prospective open-label multicenter trial executed at three peripheral centers of the Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH. The study was approved by the Institutional Ethics Committee of all the three participating centers and was done in accordance with the World Health Organization Good Clinical Practice Guidelines. The clinical trial has also been registered in the Clinical Trial Registry of India (CTRI/2012/03/002524).

Study Participants

A total of 150 participants were to be enrolled in the trial, 50 from each of the three centers, viz., Central Ayurveda Research Institute for Respiratory Disorders, Patiala, M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur, and Central Ayurveda Research Institute for Hepatobiliary Disorders, Bhubaneswar. Patients were screened in accordance with the inclusion and exclusion criteria mentioned in the protocol. A total of 103 patients following the screening criteria were recruited in the study after obtaining written informed consent.

Inclusion Criteria

Patients of either sex aged between 15 and 60 years, with hemoglobin ranging from 8 gm% to 10 gm% and who were willing to participate in the study for 14 weeks.

Exclusion Criteria

Patients suffering from thalassemia major, aplastic anemia, or sickle cell anemia were excluded from the study. Moreover, patients with evidence of malignancy, patients suffering from any other major systemic illness necessitating long-term therapy, patients with past history of atrial fibrillation, coronary artery disease, acute coronary syndrome, myocardial infection, stroke, or severe arrhythmia in the last 6 months were also excluded. Further, symptomatic patients with clinical evidence of heart failure, patients with poorly controlled hypertension defined as systolic blood pressure of >160 mm Hg and diastolic blood pressure of >100 mm Hg were also excluded. Patients with blood sugar fasting level of >250 mg/dL also fell in our exclusion range.

Patients on prolonged (≥6 weeks) medication with corticosteroids, antidepressants, anticholinergics were excluded from the study to safeguard the outcomes of the study medications. Patients with concurrent serious hepatic disorder defined as aspartate aminotransferase and/or alanine aminotransferase, total bilirubin, alkaline phosphatase >2 times the upper normal limit, or renal disorders defined as serum creatinine >1.2 mg/dL, total serum cholesterol and/or serum triglycerides >250 mg/dL, severe pulmonary dysfunction, uncontrolled bronchial asthma, and/or chronic obstructive pulmonary disease were also excluded. Alcoholics or drug abusers, pregnant and lactating women, and patients who have the past record of hypersensitivity to any of the ingredients of trial medications were also excluded. Patients who have participated in any other clinical trial during the past 6 months were also excluded from the study.

Study Interventions

The study medications included *Punarnavadi Mandura*[4] in the dose of 500 mg (two tablets of 250 mg) twice daily given with water for a period of 12 weeks and *Dadimadi Ghrita*[5] in a dose of 10 gm twice daily given orally

before food, with lukewarm water. Both the Ayurvedic formulations were procured from Good Manufacturing Practice-certified Ayurvedic Pharmaceutical industries and standardized following the standard laid in Ayurvedic Pharmacopoeia of India. Deworming was done only in the patients who had worm infestation. Patients were also guided regarding *pathya–apathya* and about iron-rich food items.

Study Procedure

On the enrolment day at baseline (visit 1), patient's demographic profile, medical history, family history particularly related to iron deficiency anemia, *sharirik prakriti*, and vital parameters were recorded. Subsequent visits were planned at an interval of 2 weeks [14th day (visit 2), 28th day (visit 3), 42nd day (visit 4), 56th day (visit 5), 70th day (visit 6), and 84th day (visit 7)]. Patients were assessed and given study medications at each subsequent visit till 84th day. There was also a without medication follow-up after 2 weeks of 84th day visit. Details of clinical assessment and study schedule are given in Flow Chart 1.

At the study site, data of all the patients were recorded in predesigned case report forms (CRFs) and was also entered in electronic formats (e-formats) designed in MS-Excel with many data validation checks to ensure correct data entry. The e-formats and xerox of the CRFs along with the laboratory investigation reports of the patients were sent by the participating centers to the Council's headquarters on a weekly basis for the purpose of clinical trial monitoring.

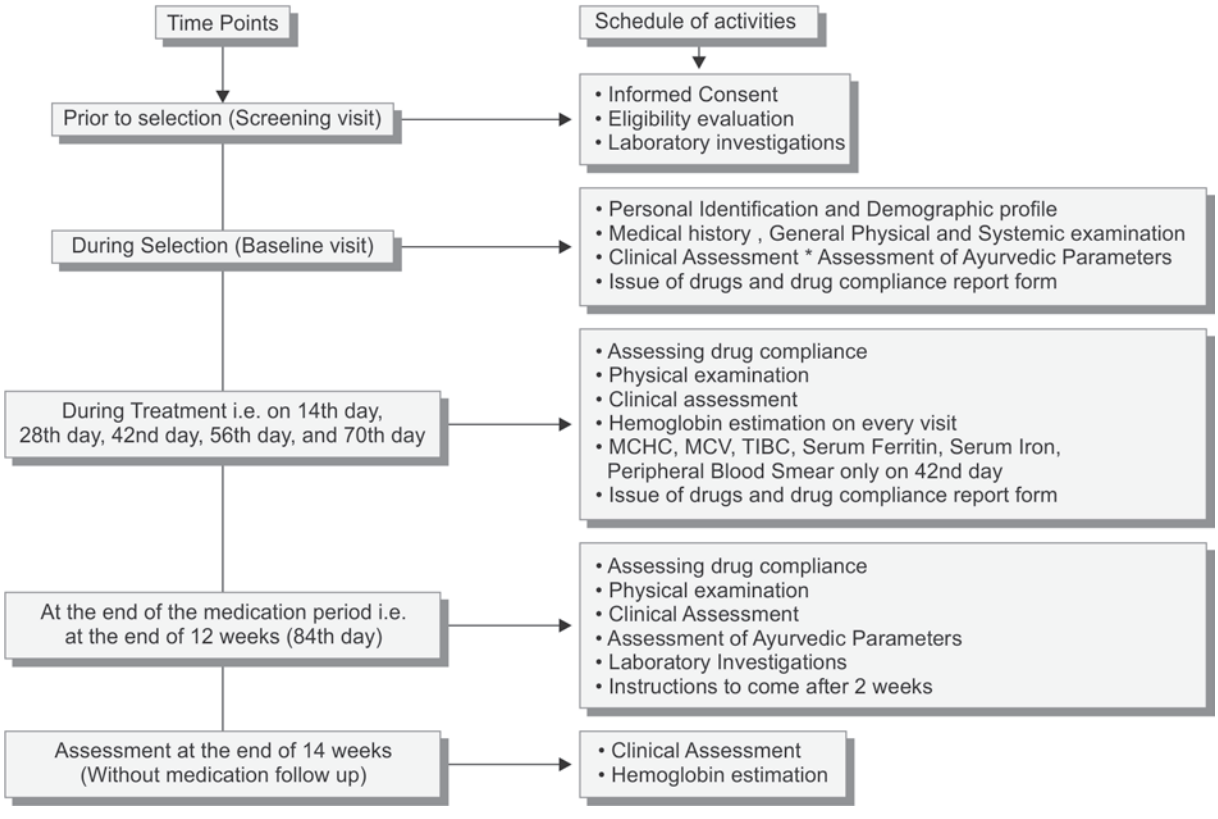
Out of the total 103 patients enrolled in the study, 38 dropped out during the course of the study. Intention-to-treat analysis was done, and the data of all those patients who have completed at least 14th day visit were imputed by last observation carried forward method (LOCF). Patients who dropped out after baseline visit only were excluded from analysis. Hence, data of a total 90 patients were used for statistical analysis. Flow Chart 2 shows the outflow of the patients in the study.

Outcomes

Primary outcome measure was mean change in hemoglobin level at 84th day from baseline. The secondary outcome measures was mean change in serum ferritin level, change in peripheral blood smear, and relief in symptoms like weakness, fatigue, dizziness, headache, palpitation, shortness of breath, irritability, taste disturbances, pallor, brittle nails, pica, glossitis, angular stomatitis, and ringing in the ears at 84th day as compared with baseline.

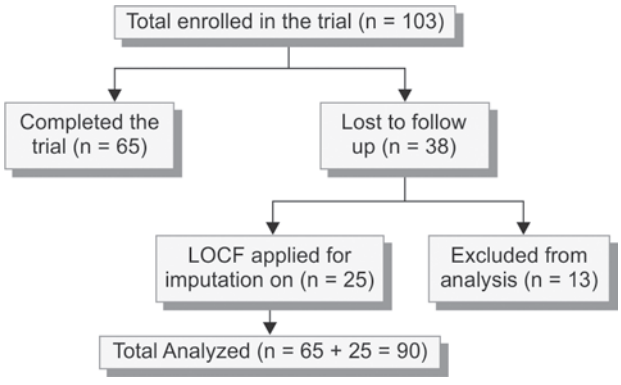
Statistical Analysis

Primary outcome and secondary outcome measures, i.e., hemoglobin and serum ferritin, were analyzed as mean change in the response from baseline to 84th day by



MCHC: Mean corpuscular hemoglobin concentration; MCV: Mean corpuscular volume; TIBC: Total iron-binding capacity

Flow Chart 2: Outflow of the patients in the study



using paired t-test. A p-value of <0.05 was considered significant. Symptomatic relief was assessed as percentage change in terms of presence of any symptom at baseline and at 84th day. All statistical analysis was performed using Statistical Package for Social Sciences version 15.0.

RESULTS

Data of a total 90 patients (8 males and 82 females) were used for statistical analysis. Out of these, maximum patients [31 (34.4%)] were in the age group of 15 to 25 years. Table 1 shows the demographic profile of the patients. Fifty-five (61.1%) patients were of *Vataja-pittaja sharirik prakriti*. Vital parameters of the patients recorded at baseline of the patients are shown in Table 2. Mean systolic blood pressure was 112.47 mm Hg and mean diastolic blood pressure was 70.76 mm Hg.

It was also observed from the data that 60 (66.7%) of the patients were married; 71 (78.9%) of the patients were literate enough to read and write. Maximum number of patients [46 (51.1%)] were housewives and were involved in domestic work which included physical labor also. Maximum numbers of patients were residing in urban area

It was also noticed that 55 (61.1%) patients were vegetarians, addiction of any kind was not found in 95.6% of cases, while smoking and chewing tobacco were observed in 2.2% of cases each; 97.8% of the cases were nonalcoholic and 2.2% had the habit of taking alcohol occasionally.

Significant effect of *Punarnavadi Mandura* and *Dadimadi Ghrita* was also seen on the common complaints faced by patients suffering from iron deficiency anemia. The complaint of weakness was observed in 89 patients at baseline, which reduced by 25%, and was found only in 66 patients at the end of treatment. Complaint of fatigue reduced in 43.8% patients and dizziness reduced in 68.5% patients. A significant reduction was also seen in the complaint of headache, which reduced in 75.08% patients. The effect of the trial medications *Punarnavadi Mandura* and *Dadimadi Ghrita* on other complaints faced by patients of iron deficiency anemia is shown in Table 3.

Table 1: Demographic profile of the patients

Demographic profile (n = 90)	
Age group (years)	
15–25	31 (34.4)
26–35	18 (20.0)
36–45	25 (27.8)
46–55	11 (12.2)
56–60	5 (5.6)
Sex	
Male	8 (8.9)
Female	82 (91.1)
Marital status	
Married	60 (66.7)
Unmarried	29 (32.2)
Widow(er)	01 (1.1)
Educational status	
Illiterate	19 (21.1)
Read and write	71 (78.9)
Socioeconomic status	
Above poverty line	73 (81.1)
Below poverty line	17 (18.9)
Habitat	
Urban	56 (62.2)
Semiurban	22 (24.4)
Rural	12 (13.3)
Sharirik prakriti	
Vataja	01 (1.1)
Pittaja	01 (1.1)
Vata-Pittaja	55 (61.1)
Vata-Kaphaja	02 (2.2)
Pitta-Kaphaja	28 (31.1)
Sannipataja	03 (3.3)

Values are expressed as n (%)

Table 2: Distribution of patients according to physical parameters

Physical parameters (n = 90)	
Height (m)	1.54 (0.07)
Weight (kg)	52.8 (12.82)
Respiratory rate (per minute)	19.8 (3.39)
Pulse rate (per minute)	78.6 (7.85)
Blood pressure (mm Hg)	
Systolic	112.47 (15.41)
Diastolic	70.76 (8.36)

Values are expressed as mean (standard deviation)

Effect of the study medications was also assessed by paired t-test on hematological parameters compared at baseline and at 84th day. Table 4 shows the results of the analysis on hematological parameters. Mean hemoglobin (g/dL) level increased from a baseline value of 9.29 to 9.40 at 84th day, which was, however, not statistically significant. A significant increase in mean serum iron (µg/dL) level (p = 0.005) was also seen, which rose from baseline value of 41.13 to 50.02 at the end of the treatment period (Graph 1).

Table 3: Effect of the treatment on chief complaints

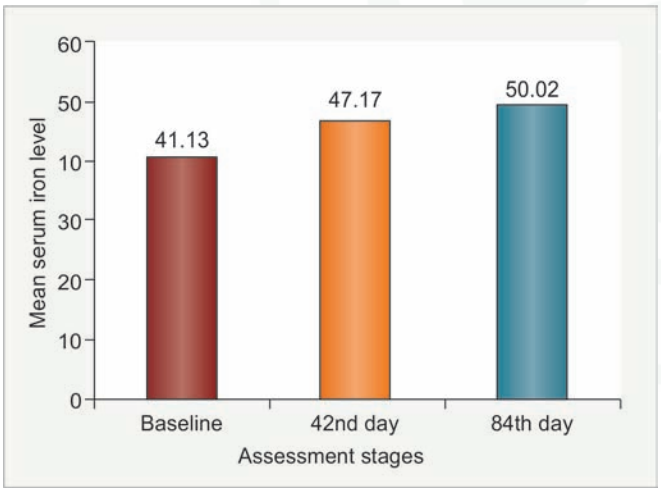
Chief complaints (n = 90)	*Baseline*	*84th day*	*Follow-up at the end of 14th week*
Weakness	89 (98.9)	66 (73.3)	64 (71.1)
Fatigue	89 (98.9)	50 (55.6)	40 (44.4)
Dizziness	54 (60.0)	17 (18.9)	14 (15.6)
Headache	52 (57.8)	13 (14.4)	14 (15.6)
Palpitation	29 (32.2)	8 (8.9)	7 (7.8)
Shortness of breath	21 (23.3)	8 (8.9)	9 (10.0)
Irritability	47 (52.2)	12 (13.3)	9 (10.0)
Taste disturbances	18 (20.0)	6 (6.7)	6 (6.7)
Pallor	54 (60.0)	39 (43.3)	39 (43.3)
Brittle nails (spoon-shaped)	1 (1.1)	0 (0.0)	0 (0.0)
Pica	10 (11.1)	3 (3.3)	2 (2.2)
Glossitis	19 (21.1)	3 (3.3)	3 (3.3)
Angular stomatitis (sores at corners of the mouth)	10 (11.1)	2 (2.2)	2 (2.2)
Ringing in the ears	14 (15.6)	1 (1.1)	0 (0.0)

Values are expressed as n (%)

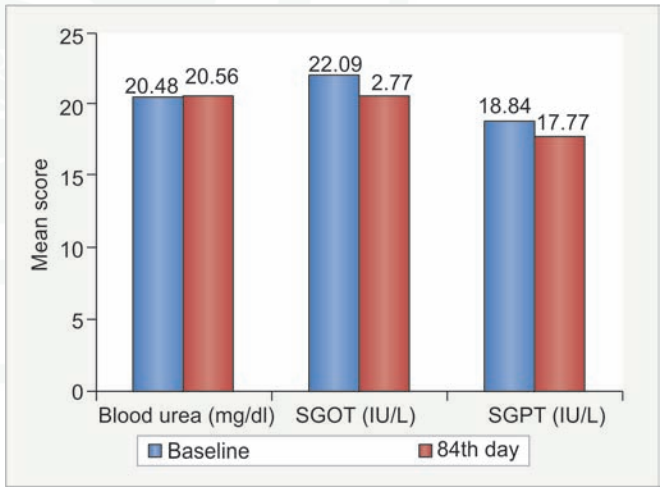
Table 4: Effect of the treatment on hematological parameters

Parameters (n = 90)	*Baseline*	*42nd day*	*84th day*	*Follow-up at the end of 14th week*	*t-value*[$]	*p-value*
Hb (gm/dL)	9.29 (0.679)	9.32 (1.266)	9.40 (1.227)	9.46 (1.278)	0.989	0.325
MCHC (g/dL)	29.77 (1.579)	30.06 (4.710)	29.32 (2.202)		2.297	0.024*
MCV (fl)	78.71 (10.829)	75.37 (14.290)	76.05 (11.591)		2.906	0.005*
PCV (%)	31.76 (2.515)	31.32 (4.092)	31.87 (3.000)		0.399	0.691
Serum ferritin (ng/mL)	23.23 (30.905)	22.73 (34.465)	19.23 (28.739)		2.358	0.021*
Serum iron (µg/dL)	41.13 (26.498)	47.17 (29.579)	50.02 (31.877)		2.857	0.005*
TIBC	430.52 (115.346)	413.57 (121.788)	417.18 (114.312)		1.032	0.305

Values are expressed as mean (standard deviation), [$]Compared using paired t-test at baseline and 84th day, *p-value <0.05 has been considered as significant; Hb: Hemoglobin; MCHC: Mean corpuscular hemoglobin concentration; MCV: Mean corpuscular volume; PCV: Packed cell volume; TIBC: Total iron-binding capacity



Graph 1: Effect of the treatment on serum iron levels



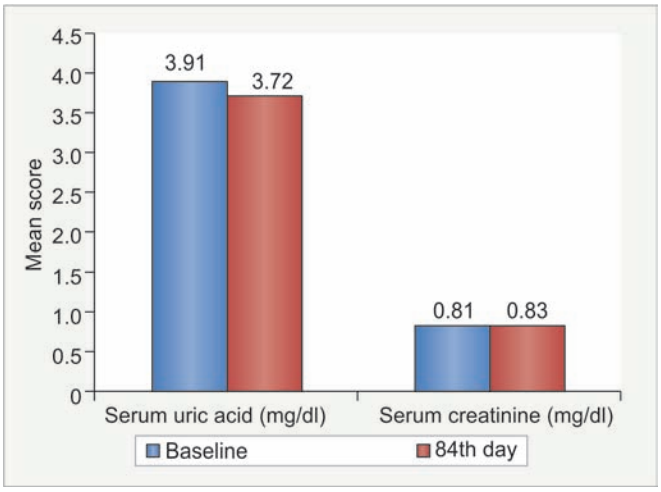
Graph 2: Effect of the treatment on safety parameters [blood urea, serum glutamic oxalocetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT)]

Safety Profile

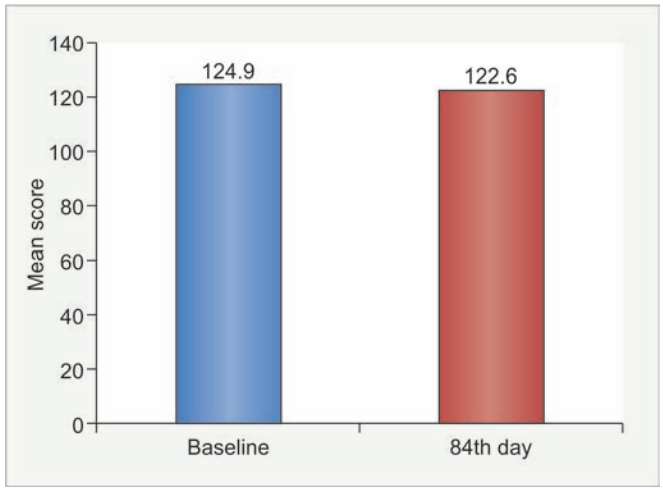
The effect of this treatment on various safety parameters, such as liver function tests and renal function tests, was assessed on baseline and at 84th day visit. The values were within limits during the entire trial period (Graphs 2 to 4). Table 5 shows the effect of the drugs on the safety parameters

DISCUSSION AND CONCLUSION

Iron deficiency anemia is very common in Indian population. The causes are nutritional deficiency, reduced bioavailability of iron, and chronic blood loss due to one or the other reason. Ayurveda is the oldest recorded medical science and it has dealt with anemia as *Pandu*



Graph 3: Effect of the treatment on safety parameters (serum uric acid and serum creatinine)



Graph 4: Effect of the treatment on safety parameters (serum alkaline phosphatase)

Table 5: Effect of the treatment on safety parameters

Parameters (n = 90)	*Baseline*	*84th day*	*t-value*[$]	*p-value*
Blood urea (mg/dL)	20.48 (5.02)	20.56 (5.07)	0.193	0.847
Serum uric acid (mg/dL)	3.91 (1.11)	3.72 (1.02)	3.068	0.001*
Serum creatinine (mg/dL)	0.81 (0.09)	0.83 (0.11)	1.504	0.136
SGOT (IU/L)	22.09 (5.63)	20.77 (6.51)	2.349	0.021*
SGPT (IU/L)	18.84 (8.14)	17.77 (6.15)	1.499	0.138
Total protein (g/dL)	7.34 (0.51)	7.32 (0.54)	0.484	0.629
Serum albumin (g/dL)	4.40 (0.52)	4.35 (0.52)	1.603	0.113
Serum globulin (g/dL)	2.93 (0.46)	2.95 (0.54)	0.551	0.583
Conjugated bilirubin (mg/dL)	0.30 (0.29)	0.29 (0.24)	0.165	0.870
Unconjugated bilirubin (mg/dL)	0.53 (0.42)	0.43 (0.27)	3.269	0.002*
Serum alkaline phosphatase (U/L)	124.89 (88.23)	122.60 (90.40)	0.394	0.694

Values are expressed as mean (standard deviation), [$]Compared using paired t-test at baseline and 84th day; *p-value <0.05 has been considered as significant; SGOT: Serum glutamic oxalocetic transaminase; SGPT: Serum glutamic pyruvic transaminase

disease owing to its symptomatic similarity. A number of formulations have been mentioned in Ayurveda classics for the treatment of *Pandu* and studies have been carried out on some of the formulations.[6-9] This project is also an effort to clinically evaluate the efficacy and safety of *Punarnavadi Mandura* and *Dadimadi Ghrita* mentioned in Ayurvedic Pharmacopoeia of India.

It was noticed from the data that maximum number of patients were females. This may be due to the fact that the iron loss in the form of monthly menstruations, pregnancies, and lactation is rampant in females of reproductive age.

Further, it was also noteworthy that the levels of serum iron increased significantly in the study, with a decrease in serum ferritin levels, which suggests that the total iron content of *Punarnavadi Mandura* and *Dadimadi Ghrita* is comparable with conventional iron therapies.

Significant decrease in serum ferritin and decrease in total iron-binding capacity suggest that sufficient amount of iron is present in serum, which is required for formation of RBCs. However, hemoglobin level has not increased markedly in the study, which may be due to shorter intervention period. The life of RBCs is 120 days; hence, in the future, long-term studies with larger sample size may be taken up to further validate the efficacy of these interventions.

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सारांश

पाण्डु की चिकित्सा में पुनर्नवादि मंडूर तथा दाडिमाद्य घृत की आतुरीय प्रभावकारिता एंव सुरक्षा–एक प्रत्याशित बहुकेन्द्रीय ओपन लेबल अध्ययन

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[12]एम एम पाढी, [13]करतार सिंह धीमान

भूमिका: लौह तत्व की कमी से होने वाली यह व्याधि विश्व में बहुत व्याप्त रूप से पाई जाती है इसे कुपोष्ण जन्य व्याधि भी कहा जाता है जिसका कारण बहुमुखी है। सामान्यत: यह व्याधि शरीर में लौह तत्व की कमी के कारण होती है इसकी लक्षणों के आधार पर पांडु से तुलना कर सकते है।

उद्देश्य: 'दाड़िमादि घृत' व 'पुर्ननवादि मंडूर' के प्रभाव एंव सुरक्षा को पांडु रोगियों में अध्ययन करना।

साधन एंव विधि: यह एक बहु केन्द्रीय अध्ययन है जो कि केन्द्रीय आयुर्वेदीय अनुसंधान परिषद् के 3 केन्द्रों पर 103 रोगियों में चयन प्रक्रिया के अनुसार बहिरंग विभाग में किया गया तथा इन रोगियों को पुनर्नवादि मंडूर (500 मिली ग्राम) व दाड़िमादि घृत (10 ग्राम) दिन में दो वार भोजन से पूर्व उष्ण जल के साथ 12 सप्ताह तक दिया गया। साथ ही रोगियों को बिना औषधि दिए 12 सप्ताह के पश्चात 2 सप्ताह तक और निरीक्षण किया गया। 103 में से केवल 90 रोगियों के आकड़ों का ही आकंलन किया गया है। इनमे से एच.बी., एम.सी.एच., टी.आई.बी.सी., सीरम फेरिटिन और सीरम आयरन आदि की पहले दिन, 42वे दिन एंव 84 दिन पर जाँच की गई। इसमें महत्वपूर्ण परिणाम प्राप्त हुआ।

परिणाम: 84 दिनों के समाप्त होने पर सीरम आयरन में वृद्धि पाई गई। पांडु के लक्षणों में भी जैसे कि दौर्बल्य, थकान, चक्कर आना, सर दर्द आदि में भी लाभ प्राप्त हुआ। अत: यह चिकित्सा पांडु रोग में प्रभावकारी एंव सुरक्षित सिद्ध हुई। इसके अन्तर्गत कोई भी दुष्प्रभाव नहीं प्राप्त हुआ।

निष्कर्ष: दाड़िमादि घृत व पुनर्नवादि मंडूर के पांडु रोग की चिकित्सा में प्रभावकारी एंव सुरक्षित परिणाम प्राप्त हुए।