Effect of Ayurveda Medications (Kasīsa Bhasma and Dhārī Avaleha) on Iron Deficiency Anaemia: A Randomized Controlled Study

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Original Article

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Abstract

Background: This paper explores the role that Ayurveda can play in the management of Iron Deficiency Anaemia, a major nutritional deficiency disorder affecting people across the globe. **Methodology:** Forty (40) patients suffering from Iron deficiency anaemia as per WHO guidelines, between the age group of 20 to 60 yrs of either sex participated in the study. Study was a randomized, controlled, open label clinical study. Patients were randomly divided into two groups: Group D (n = 20) received Dhātrī avaleha 10 g twice a day after food. Group K (n = 20) received capsules Kasīsa bhasma 125 mg thrice a day. Both interventions were administered for 30 days and the subjects were followed up for next 30 days with placebo capsules to assess the sustainability of the effects. Assessments were done at baseline, 30th and 60th days. Primary outcome measure was hemoglobin estimation (Hb) and secondary outcome measures were the other hematological parameters such as Red blood cell (RBC) indices, total RBC count, Packed Cell volume (PCV) and Peripheral Blood smear study. **Results:** Both interventions produced significant improvements ($P < 0.001$). *Kasīsa bhasma* was better compared to *dhātrī avaleha* in terms of primary ($P < 0.0001$) and secondary outcomes. Comparison of outcomes from base line – 30th day, base line – 60th day and 30th – 60th day showed significant ($P < 0.0001$) improvement in both the groups in parameters such as haemoglobin, MCV and MCH. Hence improvements sustained during placebo intervened sustainability period also. **Conclusions:** Study effectively shows that Kasīsa bhasma is better then *Dhātrī avaleha*. Improvements by both interventions were sustained even during the sustainability period.

Key Words: *Ayurveda, dhātrī avaleha, haemoglobin, iron deficiency anaemia, kasīsa bhasma*

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Introduction

Anaemia is a major global public health problem with consequences on human health, social and economical development. Anaemia can be caused due to multiple factors but one of the major factors is nutritional deficiency. IDA is the most significant contributor of all anaemias and hence IDA and anaemia are often used synonymously. Around 30–52% of nonindustrialized population has anaemia in general and iron deficiency in particular.[1] Iron deficiency and IDA were considered as one among the top 10 risks globally and regionally,[2] contributing to the 14th leading cause of disease burden in the world global burden of diseases.[3] IDA causes 8.4 lakh deaths and 35 million cases of disability adjusted life years (DALYs).[4]

In India, surveys have shown high prevalence of anaemia.[5] Anaemia prevalence was 56.2 percent in women of 15–49 yrs of age, 79.2 percent among children aged 6-35 months, 57.9 percent in pregnant women and 24.3 percent in men aged 15-49 yr. Sex prevalence shows that 55% of women and 25% of men suffer from anaemia.[6] It has been estimated that iron deficiency costs India about 5 percent of its gross national product (GNP) annually from loss of lives, resources and productivity.[7]

The main reasons for IDA have been determined to be inadequate intake of iron, low bioavailability of dietary iron from plant foods due to inhibitory factors, low levels of absorption enhancers in the diet, repeated pregnancies, increased needs during growth and development among children and adolescents, parasitic infestations and chronic blood loss. Poverty compounds these factors through inadequate access to dietary diversity, safe water, knowledge about safe food handling and proper feeding practices.[8]

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Anaemia and iron deficiency is known to have several functional consequences. IDA adversely effects cognitive performance, behavior, physical growth in children. IDA during pregnancy increases the perinatal risks of mother and infant. Overall increase in infant mortality, decreased functioning of immune system, reduced work capacity and productivity, endocrine and neurotransmitter abnormality associated with triiodothyronine, thyroid function general, production and metabolism of catecholamines. increased risk of heavy metal absorption.[9]

Preventive strategies are through food based approaches that cause multi nutritional benefit. Foods rich in iron such as meat, organs of cattle, fish, poultry, legumes and green leafy vegetables are beneficial. Enhancers of Iron absorption such as haem iron of animal origin, ascorbic acid or Vitamin C and inhibitors of Iron absorption like phytates of cereal grains, legumes, nuts, seeds, iron-binding phenolic compounds (tannins) in tea, coffee, calcium of milk and milk products play a determining role. Conventional approach for IDA is through Iron Supplements such as ferrous sulphate etc., However, adherence to the medication is difficult due to various side effects such as epigastric discomfort, nausea, diarrhoea, or constipation.[1] Side effects can be minimized by drug intake along with food, however, doing this reduces the iron absorption by 40%.[10] Iron preparations inhibit the absorption of other drugs such as tetracyclines, sulphonamides, and trimethoprim.[1] Hence there is a need to look for newer agents which have a better therapeutic utility.

Complementary and alternative systems (CAM) or traditional Medicines (TM) which are widely used by the ailing community needs to be explored. In countries such as Republic of Korea and China, in spite of well established conventional health care 86% and 90% of population commonly use TM.[11] Ayurveda has analysed the different types of anemia under the classification of Pandu roga.[12] Ayurveda has indicated use of various herbal formulations like dhātrī avaleha[13] and iron formulations such as Loha bhasma, Maṇḍura bhasma, Mākṣika bhasma, Gairika, Vimala and Kasīsa[14] for this ailment. Hence the present study was designed with an objective to evaluate effect of a noniron formulation, Dhātrī avaleha with an iron formulation Kasīsa bhasma in patients of IDA. The study was also aimed to evaluate the sustainability effect of the drugs.

Methodology

Aims and objective

To evaluate the effect of *Dhātrī avaleha* in patients of Iron Deficiency Anaemia.

The null hypothesis states that there is no difference in clinical outcome of *Dhātrī avaleha* on IDA when compared to the standard drug *kasīsa bhasma*.

Patients attending outpatient department of the institute were recruited for the study. The CONSORT statement guidelines has been followed in reporting the outcomes of the study.[15]

Patients

Forty patients diagnosed as having Iron deficiency anaemia as per the WHO criteria[16] were recruited from OPD and IPD of the SDM College of Ayurveda, Udupi, Karnataka, India.

Inclusion criteria

1. Haemoglobin percentage below the range of 8 g/deci Liter (dL)
2. Age group: 20–60 yrs
3. Blood picture – Microcytic hypochromic, Normocytic hypochromic cells
4. Informed written consent.

Exclusion criteria

1. Anaemia from other disorders such as Hepatic cirrhosis, Rheumatoid Arthritis, Uraemia, Malignant disorders etc
2. Sideroblastic anaemia, Thalassaemia major and minor
3. Haemoglobin levels below 5 g/dl
4. Comorbid medical or surgical disorders
5. Female patients who are pregnant or lactating
6. Patients with a history of alcohol, tobacco addiction etc
7. Patients on any other medications or health supplements since 4 weeks.

Screening measures

All the patients were thoroughly screened for Iron deficiency anaemia. Assessments of patients were through an extensive clinical examinations and on Ayurvedic parameters such as *prakṛti* and other laboratory parameters.

The following laboratory investigations were carried out at Clinical Laboratory, SDM Ayurveda Hospital Udupi in all patients at baseline, 30th and 60th days of intervention: Blood investigation-Haemoglobin concentration, Total RBC count, Total Leukocyte count, Differential Leukocyte count, Peripheral Blood smear study, Haematocrit (PCV) and Stool examination for ova and cysts. In addition to the above, we conducted other investigations such as Clotting Time, Bleeding Time, Liver Function Test, Renal Function Test, Sonography of abdomen etc., as and when required to rule out co morbidities.

Research design

The present study is a randomized, controlled, open label, parallel group comparative clinical study. The scholars involved in randomization, distribution and administration of study articles were independent from the investigators. Computer generated random numbers were utilized for the study. Block size was 4. During study, patients were asked to adhere to the treatment protocol and report any

adverse events to the investigators at the earliest. Any clinical manifestation that was likely to cause considerable distress was screened for possible adverse events. All patients were subjected to *dīpana-pācana* (increasing the metabolic activity) and *koṣṭha śodhana* (cleansing of gut using mild laxatives) procedures, which is a standard preparatory procedure[17] in Ayurveda before starting any medication. *Dīpana – pācana* was done using *Pañcakola* ciūrṇa[18] 5 g three times a day, before meals, for 3–7 days with hot water, till the desired manifestations such as lightness of body, proper evacuation of flatus, urine, feces, feeling of purity in heart, eructation, feeling of normalcy and purity in throat and mouth, disappearance of drowsiness and exertion, appetite for food[19] were observed in the patient. *Koṣṭha śuddhi* (cleansing of gut) was done with administration of *śuddhi cūrṇa*[20] 5 g at bed time, with water. Later, all patients were randomized into two groups through block randomization procedure. Patients in Group D received *Dhātrī avaleha* 10 g twice a day after food with water. Patients in Group K received *Kasīsa bhasma* capsules 125 mgs, thrice a day, after food, with water. *Dhātrī avaleha*[21] and *Kasīsa bhasma* dosages[22] were as per the classical literature. Ingredients of the formulations were procured from authentic distributors and formulations were prepared in GMP approved SDM Ayurveda Pharmacy Udupi as per the standard procedures. Total duration of study was for 2 months in which interventions with Ayurveda medication was for one month. For an additional one month, observations were maintained with a starch placebo capsules of 250 mg thrice a day. Assessments were done at baseline, 30th day and 60th day of interventions [Figure 1]. The nature and design of the study were explained to patients, and informed consent was obtained. The study was approved by the Institute Ethics Committee (Protocol Id-SDM/99/KC/BRT, SDM College of Ayurveda Udupi, Date of Approval-10.1.2000. CTRI Registration Number-REF/2015/08/009513). Convenient sample of 20 patients in each group were selected.

Assessments

1. Primary outcome – Hemoglobin (g/dL)
2. Secondary outcome - Blood parameters such as total Red Blood Cell (RBC) count, Size of RBC (Anisocytosis), Shape of RBC (Poikilocytosis), Chromasis of RBC, Packed Cell Volume (PCV), Mean Corpuscular volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin concentration (MCHC).

Statistical methods

Statistical analysis was carried out using SPSS Version 15.0. Homogeneity of the data across the groups was evaluated by the χ^2 test. Comparison of groups across different time points was carried out by repeated-measure analysis of variance (ANOVA) with Tukey post-hoc test. Comparison of groups at baseline was by one-way ANOVA

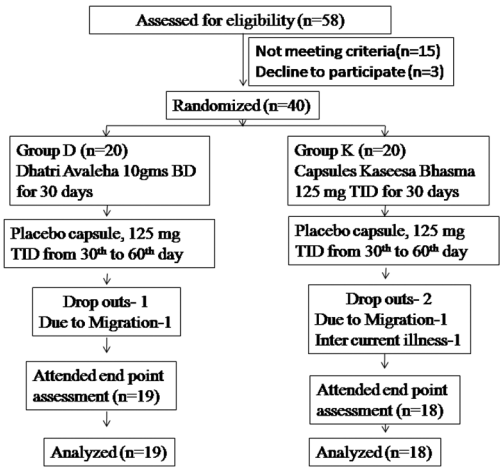

Figure 1: Subject flow chart through the study

with Tukey posthoc test. Effect size was calculated by Partial Eta Square method to assess the effect of treatment through the outcome from baseline to 30th and 60th day of treatment. The criteria used for interpreting effect size measures were as follows: 0–0.2 = minimal, 0.2–0.5 = small, 0.5–0.8 = medium and above 0.8 = large effect size.[23] Values are reported as mean ± 1 standard deviation. All tests were considered statistically significant at $P < 0.05$.

Results

A total of 40 patients were recruited and divided in to two groups. One patient from Group D and two patients from group K dropped out from the study. Drop outs were due to their illnesses such as typhoid needing other medications. In one case it was due to the patient having shifted to a different place. No adverse effects were reported in any of the patients [Figure 1].

Subject characteristics

Most of the patients in our study were young (28.24 ± 7.53 yrs), females (62.5%), married (65%), from rural area (65%), high school educated (37.5%), lower middle class (47.5%), mixed diet (67.5%), body constitution of *vāta pittaja prakṛti* (60%), duration of current manifestations (7.6 ± 5.93 months) [Table 1].

Primary out come-hemoglobin

Repeated measure ANOVA with time as within subject factor and groups as between subject factor showed a significant effect of time F(2,70) =217.130, $P < 0.001$. Both groups showed significant improvement that sustained during the course of the treatment. There was a significant effect of group F(1, 35) =37.583, $P < 0.001$ or group X time interaction F(2, 70) =11.233, $P < 0.001$. *Post hoc* analysis revealed at the end of 30 days and 60 days group K showed significant improvement ($P < 0.0001$) compared to group D [Table 2a and Figure 2].

Table 1: Patient profile - expressed in mean, standard deviations and percentage

Clinical profile	Group D, *n* (%)	Group K, *n* (%)	Total (%)	*P*
Age (years)	34.05±13.78	36.90±13.81	35.47±13.69	0.915
Sex				
Male	7 (35)	8 (40)	15 (37.5)	0.744
Female	13 (65)	12 (60)	25 (62.5)	
Socioeconomic status				
Poor	3 (15)	4 (20)	7 (17.5)	0.91
Lower middle class	9 (45)	10 (50)	19 (47.5)	
Upper middle class	7 (35)	5 (25)	12 (30)	
Rich	1 (05)	1 (5)	2 (5)	
Habitat				
Urban	8 (40)	6 (30)	14 (35)	0.507
Rural	12 (60)	14 (70)	26 (65)	
Food				
Vegetarian	7 (35)	6 (30)	13 (32.5)	0.736
Mixed	13 (65)	14 (70)	27 (67.5)	
Prakurti (body constitution)				
Vatakapha	6 (30)	6 (30)	12 (30)	0.885
Pittakapha	2 (10)	3 (15)	5 (12.5)	
Vatapitta	12 (60)	11 (55)	23 (57.5)	
Severity (g/dL)				
Moderate (7-8)	12 (60)	14 (70)	26 (65)	0.507
Severe (<7)	8 (40)	6 (30)	14 (35)	
Duration of illness (months)	5.2±3.07	6.35±3.68	7.60±5.93	0.291
Drop outs	1 (5)	2 (10)	3 (7.5)	
Study completed	19 (95)	18 (90)	37 (92.5)	
Total	20	20	40	

Table 2a: Effect of interventions on haematological parameters

Parameters	Groups	0 days	30 days	60 days	*P* (0-30 days)	*P* (0-60 days)	*P* (30-60 days)	Effect size (0-30 days)	Effect size (0-60 days)
Hemoglobin (g/dL)	D	6.980±0.73	8.19±0.37	8.96±0.48	<0.0001***	<0.0001***	<0.0001***	−0.55	−0.594
	K	7.33±0.53	9.21±0.71	10.48±0.78	<0.0001***	<0.0001***	<0.0001***		
	P	0.075	<0.0001	<0.0001					
RBC chromasia grade	D	1.8±0.56	1.07±0.46	0.93±0.53	0.001**	0.001**	0.916	−0.13	−0.20
	K	1.50±0.61	0.57±0.51	0.29±0.47	<0.001***	<0.0001***	0.118		
	P	0.147	0.011	0.003					
Anisocytosis grade	D	1.67±0.72	1.13±0.52	0.73±0.46	0.014*	<0.0001***	0.067	−0.45	−0.51
	K	1.93±0.62	0.71±0.61	0.14±0.36	<0.0001***	<0.0001***	0.007**		
	P	0.305	0.056	0.001					
Poikilocytes grade	D	1.20±0.56	0.33±0.49	0.33±0.49	0.001**	0.001**	1.000	0.09	0.005
	K	1±0.78	0.29±0.47	0.14±0.36	0.010*	0.001**	0.483		
	P	0.434	0.791	0.246					
Target cells grade	D	0.67±0.49	0.27±0.46	0.27±0.46	0.228	0.092	1.000	−0.10	−0.22
	K	0.71±0.61	0.14±0.36	0	0.051	0.002**	0.766		
	P	0.818	0.429	0.038					
Polychromasia grade	D	0.33±0.26	0.13±0.35	0.20±0.41	0.555	1.000	1.000	0.338	−0.006
	K	0.57±0.65	0.79±0.80	0.43±0.65	0.512	1.000	0.401		
	P	0.271	0.008	0.263					
Reticulocytes count in percentage of red cells	D	1.53±0.46	1.53±0.52	1.27±0.46	1.000	0.714	0.587	−0.15	−0.30
	K	1.86±0.66	2.14±0.86	1.57±0.51	0.766	0.668	0.032*		
	P	0.152	0.028	0.103					

Expressed in mean±SD.*P<0.05, **P<0.01, ***P<0.001. SD: Standard deviation, RBC: Red blood cell

Table 2b: Effect of interventions on haematological parameters

Parameters	Groups	0 days	30 days	60 days	*P* (0-30 days)	*P* (0-60 days)	*P* (30-60 days)	Effect size (0-30 days)	Effect size (0-60 days)
Total RBC (10^{12}/L)	D	3.09±0.53	3.51±0.42	3.25±0.79	0.004**	1.000	0.409	−0.12	−0.32
	K	3.37±0.47	3.91±0.45	4.11±0.38	<0.0001***	0.003**	0.792		
	P	0.078	0.019	0.001					
PCV (%)	D	25.20±2.37	27.53±2	28.53±1.92	0.005**	<0.0001***	0.019*	−0.21	−0.61
	K	27.07±3.22	30.57±3.55	34.36±3.30	<0.0001***	<0.0001***	<0.0001***		
	P	0.06	0.008	<0.0001					
MCV (fL)	D	67.53±3.78	72.2±2.81	80.67±2.77	<0.0001***	<0.0001***	<0.0001***	−0.61	−0.51
	K	69.43±4.01	78.14±4.83	83.86±4.57	<0.0001***	<0.0001***	<0.0001***		
	P	0.201	<0.0001	0.03					
MCH (pg/cell)	D	21.27±1.98	25.47±2	27.67±1.40	<0.0001***	<0.0001***	<0.0001***	−0.39	0.04
	K	20.14±2.44	23.07±3.17	26.36±2.56	<0.0001***	<0.0001***	<0.0001***		
	P	0.136	0.021	0.096					
MCHC (g/dL)	D	27.73±1.62	28.93±1.71	30.47±1.55	0.112	0.001**	<0.0001***	−0.40	−0.20
	K	26.79±3.17	30.43±3.13	30.57±3.16	<0.0001***	<0.0001***	1.000		
	P	0.315	0.119	0.91					
Total count WBC (cells/µL/mm^3)	D	7006.67±700.48	7273.33±561.21	7306.67±602.93	0.127	0.068	1.000	−0.08	−0.13
	K	7085.71±475.94	7435.71±545.76	7514.29±473.7	0.035*	0.008*	1.000		
	P	0.727	0.437	0.314					
Eosinophils percent in differential count	D	2.73±0.46	2.33±0.72	1.47±0.74	0.310	<0.0001***	0.006**	−0.45	0.07
	K	2.43±0.85	1.07±0.47	1.29±0.73	<0.0001***	<0.0001***	1.000		
	P	0.236	<0.0001	0.513					

Expressed in mean±SD. *P<0.05, **P<0.01, ***P<0.001. SD: Standard deviation, RBC: Red blood cell, PVC: Packed cell volume, MCV: Mean corpuscular volume, MCH: Mean corpuscular hemoglobin, MCHC: Mean corpuscular hemoglobin concentration, WBC: White blood cell

Secondary outcomes

Total RBC count

Repeated measure ANOVA with time as within subject factor and groups as between subject factor showed a significant effect of time F(2,70) =10.439, $P < 0.001$. Both groups showed significant improvement that sustained during the course of the treatment. There was a significant effect of group F(1,35) =15.866, $P < 0.001$ and group X time interaction F(2, 70) =3.379, $P = 0.041$. *Post hoc* analysis revealed at the end of 30 days ($P = 0.019$) and 60 days ($P = 0.001$) group K showed significant improvement compared to group D [Table 2b and Figure 2].

PCV

Repeated measure ANOVA with time as within subject factor and groups as between subject factor showed a significant effect of time F(2,70) =83.074, $P < 0.001$. Both groups showed significant improvement that sustained during the course of the treatment. There was a significant effect of group F(1,35) =16.454, $P < 0.001$ and group X time interaction F(2,70) =12.113, $P < 0.001$. *Post hoc* analysis revealed at the end of 30 days ($P = 0.008$) and 60 days ($P < 0.001$) group K showed significant improvement compared to group D [Table 2b and Figure 3].

MCV

Repeated measure ANOVA with time as within subject factor and groups as between subject factor showed a significant effect of time F(2,70) =225.572, $P < 0.001$. Both groups showed significant improvement that sustained during the course of the treatment. There was a significant effect of group F(1,35) =9.080, $P = 0.006$ and group X time interaction F(2,70) =5.074, $P = 0.010$. *Post hoc* analysis revealed at the end of 30 days ($P < 0.001$) and 60 days ($P = 0.03$) group K showed significant improvement compared to group D [Table 2b and Figure 3].

Effect of interventions was comparable in all other parameters at different time points when assessed through repeated measure ANOVA.

Comparison within group showed that effect of interventions at the end of 30 days and 60 days was significant in most of the parameters such as Hemoglobin, Total RBC, MCV, PCV, RBC chromasia, Anisocytes, Poikilocytes, MCH [Tables 2a, b and Figures 2-4]. Hence improvement was noted even in the observation period. In Total RBC, Group D which showed improvement during medication period failed to maintain the sustained improvement when compared between 0–30 days to 30–60 days outcomes [Figure 2].

Effects of medications during placebo intervention period (30-60 days) showed significant sustainable improvement in Anisocytes and Reticulocytes in Group K. However group D showed significant sustainable effect in MCHC and eosinophils.

Effect size comparison showed that Medium effect size was seen in Hemoglobin, MCV and PCV parameters. Haemoglobin and MCV in 0–30 days and 0–60 days comparison. PCV in 0–60 days comparison. Comparisons showed that Group K was better than group D with medium effect size. Small and minimal effect size favoring group K was seen in RBC chromasia, Target cells, total RBC, MCHC in both 0–30 and 0–60 days. Eosinophils and MCH in 0–30 days periods only. Small and minimal effect size favoring group D was seen in poikilocytes in both 0-30 and 0-60 days, in periods of 0-60 days in Eosinophils and MCH parameters [Tables 2a and b].

Discussion

The present study shows that *Kasīsa bhasma* produced significant improvement than *Dhātrī avaleha* in primary outcome measure and a few of the secondary outcome measures also. Study shows that a noniron, herbal formulation viz. *Dhātrī avaleha* produces significant improvement during both intervention and sustainability period.

Kasīsa bhasma produced significant improvement in Hemoglobin, total RBC count, PCV, MCV after the period of intervention and sustainability period. However in most of the other secondary outcome measures such as RBC Chromasia, Anisocytosis grade, Poikilocytes grade, Target cells grade, Polychromasia grade, Reticulocytes count, MCH and MCHC both groups were comparable.

Within group comparison showed that both drugs produced significant improvement at the end of intervention and sustainability in most of the parameters like Hb%, total RBC count, PCV, MCV, RBC chromasia, Anisocytosis, Poikilocytes, MCH.

Comparison of sustainability of improvement among groups showed *kasīsa bhasma* to be better than *dhātrī avaleha* in

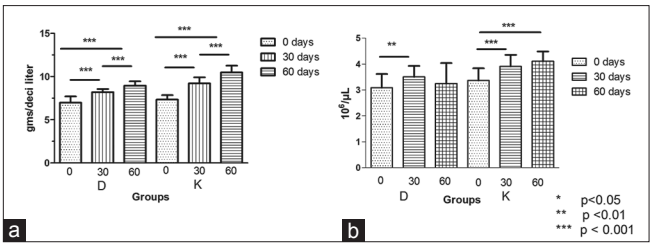

Figure 2: Changes in hematological parameters in Group D (*n* = 19) and Group K (*n* = 18) as assessed on 0 (baseline), 30th and 60th day of intervention: (a) Hemoglobin, (b) total red blood cell count. Results are expressed in mean ± standard deviation. Level of significance is **P* < 0.05, ***P* < 0.01, ****P* < 0.001

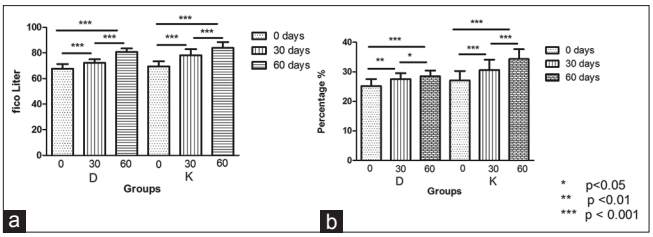

Figure 3: Changes in hematological parameters in Group D (*n* = 19) and Group K (*n* = 18) as assessed on 0 (baseline), 30th and 60th day of intervention: (a) Mean corpuscular volume, (b) packed cell volume. Results are expressed in mean ± standard deviation. Level of significance is **P* < 0.05, ***P* < 0.01, ****P* < 0.001

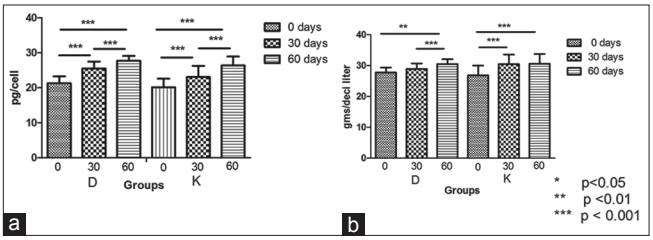

Figure 4: Changes in hematological parameters in Group D (*n* = 19) and Group K (*n* = 18) as assessed on 0 (baseline), 30th and 60th day of intervention: (a) Mean corpuscular hemoglobin, (b) mean corpuscular hemoglobin concentration. Results are expressed in mean ± standard deviation. Level of significance is **P* < 0.05, ***P* < 0.01, ****P* < 0.001

Anisocytosis, Reticulocytosis. *Dhātrī avaleha* was better only in MCHC. Effect size comparison showed medium in Hb% and MCV in both intervention and sustainability phases favoring *kasīsa bhasma* over *dhātrī avaleha*. In both the groups we did not notice any kind of adverse reactions.

Most of the patients in our study were suffering from moderate to severe anaemia.[24] Average duration of the illness was 7.6 months. Mean increase in haemoglobin with 30 days intervention of *kasīsa bhasma* was 1.88 g/dl and *Dhātrī avaleha* was 1.2 g/dl. *Kasīsa bhasma* effects on haemoglobin were comparable to the therapeutic goal of oral iron therapy of raising serum haemoglobin by 1–2 g/dl every two weeks.[25]

Better outcome of *kasīsa bhasma* can be attributed to presence of iron whose oxidative state could be ferrous state.[26] *Kasīsa* is the only Iron preparation of ayurveda to have iron in ferrous state and the oxidative status of

Iron in *Kasīsa Bhasma* remains to be studied. Studies have established importance of ferrous iron in absorption and therapeutics of Iron deficiency anaemia.[27] Bhasma is an Ayurveda metal/mineral preparation containing nano particles as a result of the processing that facilitate drug absorption in the body.[28] A previous study[29] on *śuddha Kasīsa* (pure *kasīsa*) has also showed similar results in terms of significant increase in haemoglobin, Total RBC Count, MCV, MCH, PCV. Poly herbal drug *Dhātrī avaleha* contains various ingredients such as *Vaṃśalocana* (Silicious concretion obtained from *Bambusa arundinaceae* Willd.), Śunṭhī (*Zingiber officinale* Rosc.), Madhuyaṣṭi (*Glycyrrhiza glabra* Linn), Pippalī (*Piper longum* Linn.), *Mṛdvīkā* (*Vitis vinifera*), *Śarkarā* (*Saccharum officinarium* Linn.), *Āmalakī* (*Emblica officinalis* Gaertn.), Honey. *Emblica officinalis* is one of the richest sources of ascorbic acid. Role of ascorbic acid is well established in converting ferric iron to ferrous iron and helping in its absorption in the body.[27] Ascorbic acid is specially helpful in Indian population who on an average consume more vegetarian foods with low iron bioavailability. Other herbal ingredients through their antioxidant, micro nutrients value might have helped in nutritional uptake and alleviated anemia in the patients. Interventions showed no untoward or adverse reactions. *Dhātrī avaleha* has also shown to have a potential role as an adjuvant in the management of Thalassemia.[30] Other Ayurveda formulations such as *Dhātrī loha*,[31] *Haṃsa maṇḍura*[32] and *Phalatrikādi kvātha*[32] have also shown favorable outcomes in IDA.

Improvements not only sustained in most of the parameters but also progressed during the drug withdrawn observational period. The reason for this may be the sustained long term effect of the drugs. The drugs might also have played a role in correcting the defective absorption of micro nutrients such as iron from food supplements. These drugs increase the *agni* (metabolic process) and which in turn help in correcting the deficits in the metabolism. Another study[33] has also shown the therapeutic effect and sustainability effect of Ayurveda formulations in nutritional deficiency anaemia in children.

Advantage of the *kasīsa bhasma* when compared to the conventional oral iron therapy is the lack of adverse effects. Gastrointestinal disturbances such as nausea, heartburn, pain, constipation, and diarrhoea are the most commonly reported side effects, irrespective of the type of conventional iron preparations used. This occasional intolerance is usually viewed as a limiting factor for oral iron therapy, as it may impact patient compliance.[34]

The present study highlights that Ayurveda intervention can successfully treat IDA. However, scarcity of documentation and lack of validation are few of the hindrances in their propagation. Ayurveda and other traditional medicinal systems have the potential to provide effective, economical and safer medications to IDA which has a large ailing community. A randomized, controlled, open label clinical study could effectively demonstrate the outcome. Outcomes were effectively captured in various subjective and objective parameters. A nonIron formulation, *Dhātrī avaleha* can also a play a significant role in IDA management.

This study has a few limitations such as lesser sample, shorter duration of intervention. Comparison with the currently used medications of IDA such as ferrous sulphate would have been more beneficial. Assessment of iron state by serum ferritin, Erythrocyte protoporphyrin, Serum iron, transferrin, and transferrin saturation, Serum transferrin receptors would have also added value. Detailed study of these drugs and their pharmacokinetic studies can thrŏ more light.

Conclusions

This study stresses the importance of two Ayurveda medications in the management of IDA. *Kasīsa bhasma* and a nonIron formulation, *Dhātrī avaleha* could effectively improve Hematological parameters of IDA. Improvements not only sustained in most of the parameters but also progressed in few of the parameters during the drug withdrawn observational period. Hence, these medications can play a role in refining the current strategies for IDA management.

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Conflicts of interest

There are no conflicts of interest.

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