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Sustainable Effect of Ayurvedic Formulations in the Treatment of Nutritional Anemia in Adolescent Students

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Abstract

Objectives: Anemia is a serious health problem in Indian school children. High prevalence of anemia has been reported in nonpregnant adolescent girls. An investigation was initiated to study the effect of two non-iron-containing Ayurvedic preparations—*Sootshekhar Rasa* plus *Sitopaladi Churna*—in improving nutritional anemia among adolescent students.
Design: *This was a single-blinded, randomized, controlled study.*
Setting: The study setting was Dehradun district, North India.
Subjects: The subjects comprised a total of 1646 boys and girls, aged 11–18 years, attending school in Dehradun district.
Intervention: As per World Health Organization guidelines, a total of 1322 adolescent anemic students were randomly divided into 5 groups. Students of group I (control) received starch. Group II, III, and IV students received *Sootshekhar Rasa* (SR) plus *Sitopaladi Churna* (SC) in various combinations, namely, SR 125 mg + SC 500 mg daily, SR 250 mg + SC 400 mg daily, and SR 250 mg + SC 400 mg weekly, respectively. Group V student were given iron and folic acid tablet. All the students received treatment for 90 days and were followed up for the next 180 days.
Outcome measure: The outcome measure was to evaluate the effect of *Sootshekhar Rasa* plus *Sitopaladi Churna* in improving nutritional anemia.
Results: The overall prevalence of anemia was found to be 81.3%. At baseline, the mean hemoglobin (Hb) was 97.4 ± 13.2 g/L and ranged from 96.4 ± 0.8 g/L to 98.3 ± 0.8 g/L in various groups. At end of follow-up (day 270), a significant increase in Hb levels from baseline was observed in all treatment groups; however, the Hb gain (6.9 ± 0.6 g/L) in group III and group V (3.64 ± 0.56 g/L) differed significantly from the control group. A total of 155 students dropped out of the study due to various reasons not related to treatment. No adverse side-effect of Ayurvedic medication was noted in any student.
Conclusions: We conclude that a daily dose of *Sootshekhar Rasa* (250 mg) plus *Sitopaladi Churna* (400 mg) can produce sustainable improvement of nutritional anemia in adolescent students.

Introduction

Anemia is the most prevalent nutritional problem in the world.[1] More than 2.1 billion people are anemic worldwide.[2,3] Nutritional anemia, according to the World Health Organization (WHO), is a state in which the hemoglobin concentration in the blood is lower for the age, gender, physiologic state, and altitude, as a consequence of shortage of essential nutrients, independent of the cause of this deficiency.[4,5] Nutritional anemia includes a lack of nutrients such as iron, folic acid, vitamin B_{12} and copper, and vitamins C, E, and A. Iron deficiency anemia is the most prevalent form of nutritional disorder in infancy. It also affects communities not only in developing nations but also in highly industrialized countries.[6] In the developing world, 42% of children less than 5 years of age and 53% of children 5–14 years of age are anemic.[7]

Anemia is a serious public health problem in India.[8] A national survey has reported high anemia prevalence rates of

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79.2% in children below 3 years of age and 56.2% in women aged 15–49 years.[9] An estimated 50%–95% of the anemia in India is due to iron deficiency.[10] There are few data sources on the anemia status of Indian school-going adolescents. It is not known if adolescent school-going children have the same high prevalence of anemia. Furthermore, they are a neglected group in terms of micronutrient interventions, not reached by the intervention strategies aimed at preschool children or pregnant women.[8]

A high prevalence of anemia has been reported among adolescent Indian girls.[11] Anemia reported among adolescent girls from public and government schools in Delhi was 50.8%.[12] Studies indicate that the prevalence of anemia among those 5–14 years of age is in the range of 66.7%–77%.[13,14] Vasanthi et al.[15] reported that anemia and iron deficiency were higher in rural girls as compared to urban slum adolescent girls. A study conducted on 1513 rural adolescent girls in Gujarat indicated that 61% of the girls were anemic.[16] A multicentric study carried out in 16 districts of India indicated that the overall prevalence of anemia ranged from 33% to 89% among pregnant women and more than 60% among adolescent girls.[17] Under the anemia prevention and control program of the Government of India, iron and folic acid tablets are distributed to pregnant women, but no such program exists for adolescent girls.

There is a high prevalence of anemia in school-going adolescents in the Dehradun district. Hence, the present investigation was planned to take an initiative and study the sustainable effect of the non-iron-containing Ayurvedic preparations *Sootshekhar Rasa*[18] and *Sitopaladi Churna*[19] in improving nutritional anemia in school-going adolescent boys and girls.

Subjects and Methods

Study duration

This study was conducted from February to December 2005.

Design

This was a single-blind, randomized, controlled trial.

Ethical clearance and permission

The principal and teachers of the three schools involved were given a detailed briefing on the study protocol. Prior permission was taken from the management of all three schools for conducting this study. This study was approved by the State Government of Uttrakhand and a state-level committee comprising experts from the Department of Health, Department of Ayurveda Yoga Unani Siddha & Homeopathy (AYUSH), Ministry of Health & Family Welfare, Government of India, and Department of Education & Administration was formed to approve the study protocol and periodic monitoring of the progress. Free and informed verbal consent of the students and their parents was taken before the start of study.

Analytic procedures

Hemoglobin estimation was done by the cyanmeth-hemoglobin method.[20] An internal Quality Assurance Program was carried out within the laboratory periodically for consistency. An external Quality Assurance Program was carried out by exchanging of samples with laboratory of department of Human Nutrition and Gastroenterology, All India Institute of Medical Sciences, New Delhi. Anemia was diagnosed as per WHO recommendations.[5]

Sampling

A total of 1646 school students comprising 1327 girls and 319 boys (11–18 years) was initially screened for the study from three schools in Dehradun district. The schools were Government Girls Inter College, Rajpur Road, Government Inter College, Nathuvawala and Government Inter College, Maldevta. A total of 1121 (84.4%) of girls and 218 (68.33%) boys were found to be anemic (hemoglobin <120 g/L).

Sample size

Sample size calculation showed that ≥ 222 students per group were required to distinguish a difference in hemoglobin concentration among 5 groups of ≥ 2.0 g/L at a 5% comparison-wise significance level and with a power of 90%, assuming standard deviation of change hemoglobin concentration within each group of ≤ 5.35 g/L on the basis of previous study.[21] Estimating a dropout rate of 10%, we aimed to have at least 245 anemic students per group at baseline.

Ayurvedic medicines

The composition of Ayurvedic medicines *Sootshekhar Rasa* and *Sitopaladi Churna* is mentioned in Table 1.

Table 1. Composition of *Sootshekhar Rasa*

Traditional name	*English/scientific name*	*Proportion*
Suddha Parada	Processed cinnabar	1 part
Suddha Gandhaka	Processed sulphur	1 part
Dalchini	*Cinnamomum zeylanica*	1 part
Choti Elachi	*Elleteria cardamomum*	1 part
Tej patta	*Cinnamomum tamala*	1 part
Nagkesar	*Mesua jerrea*	1 part
Shankh Bhasma	*Turbinella pyrum*	1 part
Swarna makshika Bhasam	Chalco pyrite	1 part
Ropya Bhasma	Argentum	1 part
Tamra Bhasma	Cuprum	1 part
Dhatura's seed	*Datura metel*	1 part
Suhaga	Borax sodium borate	1 part
Saunth	*Zingiber officinale*	1 part
Kali mircha	*Piper nigrum*	1 part
Choti pippal	*Piper longum*	1 part
Bhringraj swarasa	*Eclipta alba*	Q.S. (for mardana)

Composition of *Sitopaladi Churna*

Traditional name	*English/scientific name*	*Proportion*
Mishri	Sugar candy	16 part
Vanslochan	*Bambusa arumdimaceo*	8 part
Choti Pippali	*Piper longum*	4 part
Choti Elachi	*Ellettaria cardamomum*	2 part
Dalchini	*Cinnamomum zeylanica*	1 part

Quality control of medicines

The Ayurvedic medicines used for the present study were prepared by the Bharat Bhaishajya Shala Private Limited, Dehradun, using modern scientific methods (GMP) following the stringent Ayurvedic procedures as mentioned in the classic Ayurvedic text.

Bharat Bhaishajya Shala (BBS) is a private limited unit that was incorporated in 1983. It now works in conjunction with VCP Cancer Research Foundation, Dehradun. Over the years, BBS has been involved in preparation of medicines to meet in-house requirements of medication. These preparations are based on Ayurvedic traditional standards for raw materials, processing, and finished products. Raw materials thereby used meet the specifications given in various traditional texts. The processing of the drug is done in heat furnaces with programmed controls. A particle size analyzer is employed to ensure proper grinding of the medicine and the final end product is monitored by an x-ray powder diffractometer for adequate quality control.

Study design

A total of 1322 anemic students who consented for the study were divided into 5 groups by simple randomization. Few students with severe anemia ($Hb < 70.0\,g/L$) were not included in the trial and were referred for proper medical check-up. The students were blinded to their treatment assignment. Students of group I were given starch and this acted as a control group. Group II, III, and IV students received Ayurvedic preparations *Sootshekhar Rasa* and *Sitopaladi Churna* in various combinations, the details of which are given in Table 2. Group V student were given iron and folic acid tablet (IFA), which was the positive control arm. On day 0, blood samples were drawn from all subjects for Hb estimation and thereafter, Hb estimation was done on day 30, 60, 90, 170, 270 respectively. Medicine was orally administered as per the schedule given in Table 2.

Compliance

The enrolled students were followed at weekly intervals for the treatment period. The field staffs visited all the school regularly to supervise the consumption of the medicines to ensure maximum compliance.

Statistical analysis

The data were analyzed by SPSS software (version 12.0, SPSS, Chicago, IL). Mean and 95% confidence interval in each group was calculated. Paired *t* test was used to calculate the sustainable effect within the group. One-way analysis of variance was used for multiple comparisons among the groups. A χ^2 was carried out to compare anemia prevalence between genders.

Results

The prevalence of severe, moderate, and mild anemia in the present study was 1.2%, 53.5%, and 29.6%, respectively. The overall prevalence of anemia was 81.3%. The prevalence of anemia in girls (84.5%) was significantly higher than the boys (68%). The prevalence of severe, moderate, and mild anemia among girls were respectively 17 (1.2%), 710 (53.5%), and 395 (29.6%). In boys, 167 (52.3%) and 50 (15.6%) were mild and moderately anemic, respectively.

The hemoglobin concentration (mean ± SE) values of the various intervention groups are given in Table 3. At baseline, the mean hemoglobin was $97.4 \pm 13.2\,g/dL$ and ranged from 96.4 ± 0.8 to 98.3 ± 0.8 in various groups. Significant increase in Hb concentration after 30 days of treatment was observed in group III. At the end of the treatment period, significant increase in Hb concentration was noted in all treatment groups. As compared to control, group III, i.e., daily dose of *Sootshekhar Rasa* (SR) 250 mg + *Sitopaladi Churna* (SC) 400 mg and group V (receiving IFA) was found significantly better than the other 2 treatment groups. During the follow-up period (from 90 to 270 days), a significant increase in Hb was noted in groups I and IV, respectively (Table 4). At day 270, the mean gain of Hb level (g/L) in the four intervention groups II, III, IV, and V was, respectively, 2.3 ± 0.4, 6.9 ± 0.6, 1.4 ± 0.5, and 3.64 ± 0.5. The maximum Hb gain was noted in group III.

The study started with 1322 students; however, at the end of the follow-up period there were 155 dropouts. The details of students who opted out of the study are given in Table 5. No adverse side-effect of the Ayurvedic medication was recorded in any of the participants.

Discussion

High prevalence of anemia (81.3%) among adolescent school-going students observed in this study is consistent with earlier findings of Bulliyy et al.[22] among non-school-going adolescent girls from three districts of Orissa and the study of Toteja et al.[17] on the prevalence of anemia among adolescent girls in 11 states across India. DeMaeyer et al.[5] reported the prevalence of anemia in 6–12-year-old children to be 36%, while study among 5–15-year-old urban school children of Punjab was reported as 51.5%.[13] A literature survey[23] indicates that anemia prevalence ranged from 19 to 88% across five different cities in India. Verma et al.[13]

Table 2. Various Study Group and Treatment Schedule

Groups	*No. of students*	*Status*	*Intervention*	*Dose*	*Duration (days)*
I	288	Control group	Starch	Daily	90
II	277	Treatment group	SR 125 mg + SC 500 mg	Daily	90
III	263	Treatment group	SR 250 mg + SC 400 mg	Daily	90
IV	251	Treatment group	SR 250 mg + SC 400 mg	Weekly	90
V	243	Positive control	IFS[a]	Daily	90

[a]100 mg of elementary iron and 500 μg folic acid.
SR, *Sootshekhar Rasa*; SC, *Sitopaladi Churna*.

Table 3. Hemoglobin Concentration in g/L (Mean ± SE) of All Groups from Baseline to End of Study

Group	*Intervention*	*No.*	*Day 0*	*Day 30*	*Day 60*	*Day 90*	*Day 170*	*Day 270*
I	Starch	254	96.4 ± 0.8	96.1 ± 0.7	96.7 ± 0.6	97.1 ± 0.6	96.6 ± 0.6	98.2 ± 0.6
II	SR 125 + SC 500 mg once daily	245	97.6 ± 0.8	98.1 ± 0.7	98.7 ± 0.7	99.6 ± 0.6	98.0 ± 0.6	99.9 ± 0.6
III	SR 250 + SC 400 mg once daily	233	98.1 ± 0.8	100.3 ± 0.7[a]	102.5 ± 0.6[a]	105.0 ± 0.6[a]	102.6 ± 0.7[a]	105.1 ± 0.7[a]
IV	SR 250 + SC 400 mg once weekly	220	96.7 ± 0.9	96.6 ± 0.8	97.2 ± 0.6	97.1 ± 0.6	95.9 ± 0.7	98.1 ± 0.7
V	IFS daily	215	98.3 ± 0.8	97.0 ± 0.7	101.0 ± 0.7[a]	102.3 ± 0.07[a]	100.5 ± 0.7[a]	102.0 ± 0.6[a]

[a]Differs significantly [$P < 0.01$] as compared to control (group I).
SE, standard error; SR, *Sootshekhar Rasa*; SC, *Sitopaladi Churna*; IFS, 100 mg of elementary iron and 500 μg folic acid.

reported high (38%) anemia prevalence in adolescent students belonging to higher socioeconomic groups. They also found that nearly half (47.6%) of well-nourished children were anemic. In semi-urban Nepal, the prevalence of anemia in adolescent girls aged 11–18 years was found to be about 68.8%.[24] In Bangladesh, although the prevalence of anemia in adolescence girls is very high, estimates vary widely: 43% in rural girls and 20%–40% in urban girls.[25]

Our study clearly indicates that the non-iron-containing Ayurvedic preparations *Sootshekhar Rasa* and *Sitopaladi Churna* (250 mg + 400 mg) taken daily for 90 days not only improved the Hb concentration but sustained the same in the next 180 days. These results are similar to those of the earlier study carried out with daily dose of SR + SC on nonpregnant women of a reproductive age group (11–45 years) in Dehradun.[26] The 90-day-study on 119 nonpregnant anemic women indicated a maximum gain of 16.0 g/L in Hb concentration. The maximum effect of SR + SC was seen in the moderately anemic women. Similar trends are seen in the present study. Out of the three combinations of *Sootshekhar Rasa* and *Sitopaladi Churna* that were tried, group III (SR 250 mg + SC 400 mg, daily) was found to be significantly better than the other two combinations. More importantly, the gain in Hb was sustainable even after stoppage of therapy.

Evidence indicates that preventive supplementation coupled with nutritional education may be a more effective strategy associated with better compliance and improvement in iron status.[27] Before the start of this study, school students were made aware regarding nutritional anemia. After the initial screening, parents of all students who were found to be anemic were informed. It may be possible that many students may have received some extra care and dietary modification in their home because of the awareness program. The significant increase in Hb concentration observed in the controls and group IV after stoppage of therapy may be attributed to this. The other factor could be the seasonal effect. The study of Deepa et al.[28] revealed that there was considerable seasonal variation in the iron status of adolescent girls. The frequency of consumption of foods rich in blood-forming nutrients by adolescents was higher during the post–rainy season and winter as compared to summer. Hence, higher mean Hb level was recorded in adolescent girls in the winter season compared to summer. In our study, the 270-day Hb estimation was done in winter.

Table 4. Intragroup Comparison of Change in Hemoglobin Levels g/L (Mean Change ± SE)

	At end of treatment	*From end of treatment to end of follow-up*	*From start to end of follow-up*
Groups	*0–90-day*	*90–270 day*	*0–270 day*
I	0.70 ± 0.48	1.07 ± 0.43*	1.78 ± 0.43**
II	1.98 ± 0.49**	0.26 ± 0.39	2.24 ± 0.45**
III	6.89 ± 0.51**	0.08 ± 0.53	6.97 ± 0.61**
IV	0.34 ± 0.54	1.06 ± 0.04*	1.40 ± 0.5**
V	3.92 ± 0.60**	−0.28 ± 0.49	3.64 ± 0.56**

*$p < 0.05$ and **$p < 0.01$.
SE, standard error.

Sootshekhar Rasa has been mentioned in various classical Ayurvedic texts in the chapter of "*Amla pitta Rogadhikara*,"[26] which means to reduce acid in the body. *Sootshekhar Rasa* is an important medicine of *Rasa Shastra*[29] (meaning science of mercury). It is an herbo-mineral preparation and contains many medicinal herbs, namely, *Eclipta alba* (*Bhringraj*), *Cinnamomum zeylanica*, *Zingiber officinale*, etc., along with *Bhasma*[30] of silver, copper, and mercury. *Bhringraj* is used as a restorative and rejuvenative medicine in Ayurveda. It is used as a tonic for keeping the body healthy and fit. Similarly, *Sitopaladi Churna* is a traditional Ayurvedic formulation for treatment of various upper and lower respiratory tract ailments. The hypothesis of using these non-iron Ayurvedic formulations was that it may improve the absorption of iron in the gastrointestinal tract. Anemia will result when the iron demands by the body are not met by iron absorption, regardless of the reason. The gain in Hb concentration observed in this study and in an earlier study[26] conducted on nonpregnant women indicates that *Sootshekhar Rasa* and *Sitopladi Churna* may play some role in iron absorption.

Though the Ayurvedic formulation *Sootshekhar Rasa* contained processed heavy metals in it; however, no adverse side-effect was observed in any students. *Sootshekhar Rasa* and *Sitopaladi Churna* are classic Ayurvedic preparations routinely used by Vaidya in their routine clinical practice and are considered to be safe and effective. Some Ayurvedic preparations in their native form are toxic. To remove these

Table 5. Dropouts Details of Participants

Group	Category	No.	Lost to follow-up	Objection by parents	Other illness & treatment	Lack of compliance	Total
I	Boys	03	04	10	11	09	34
	Girls	31					
II	Boys	05	05	10	10	10	35
	Girls	30					
III	Boys	04	03	08	07	12	30
	Girls	26					
IV	Boys	08	05	07	07	06	25
	Girls	17					
V	Boys	06	04	08	09	10	31
	Girls	25					

toxic qualities of the metals, the preparations undergo various processes of purification (*Shodhana*, *Marana*, and *Samskara*).[31] The metal contents of the medicines are burned several times at a high temperature. This repeated cycle of burning and cooling for several times transforms the initial contents into a nontoxic form. Metals and minerals are considered nonliving, and by treating them with herbs they are converted to a living state, thereby becoming biocompatible. The same metal processed with different herbs acts on different organs in the human body. Recently, Sathya et al.[32] studied the effect of various popular Ayurvedic *Bhasmas* for chromosomal damage and single/double-strand DNA breaks by micronucleus assay and the comet assay. Despite the presence of traces of transformed toxic heavy metals in *Bhasmas*, no induction of micronuclei or DNA damage was observed. However, improper processing/manufacturing of Ayurvedic medicines may result in dangerous consequences.[33]

In the diet, the quantity of bioavailable iron is important, and this is determined by stimulation and inhibitory factors that exist within a meal.[34] Among the iron absorption stimulation factors in the diet are organic acids, in particular ascorbic acid, which is found in citrus fruits. Among the iron absorption inhibitory factors are phytic acid, which is found in fibers, whole grains, and beans;[35] oxalic acid, which is found in spinach and beetroot;[36] and tannin, which is found in tea, coffee, and chocolate.[37] Calcium, which is present in milk and dairy products,[38] and other minerals that are close to iron in the periodic table, which compete with the same intestinal absorption, also inhibit the absorption of iron.[6]

United Nations Children's Fund/WHO Joint Committee on Health Policy[39] recommended iron supplementation for all females between 10 and 49 years in countries where over 30% of the population is anemic. Studies suggested that iron and folic acid supplement given weekly twice or even once is as effective as daily supplementation in raising hemoglobin levels.[11,40,41] In the past, many daily supplementation programs in developing countries have been unsuccessful due to lack of supply and compliance.[42] Moreover, one of the problems of iron supplement is that it causes unpleasant gastrointestinal side-effects such as epigastric pain, nausea, vomiting, diarrhea, and so on. This could be one of the reasons why many subjects discontinue the intake of the supplement.[11] In the present study, no unpleasant side-effects of the Ayurvedic formulations were reported by any student. The compliance was good, though there were some dropouts, but they were not related to intervention.

World interest in adolescent health issues has grown dramatically in the past decade. However, much of the attention has been on adolescent pregnancy and sexually transmitted diseases, including human immunodeficiency virus infection, but adolescent nutrition has aroused little interest.[43] Almost 25% of India's population comprises girls below 20 years of age. Adolescent pregnancies make up 10%–15% of the total and may be largely attributed to early marriage.[44] Anemia has been related to reduced work capacity,[45] reduced ability to execute activities of daily living,[46] and poor pregnancy outcome.[47] Study shows that children with iron deficiency present worse performance in psychomotor test than do nonanemic children.[48]

Conclusions

The highest prevalence of anemia exists in the developing world where its causes are multifactorial. With limited resources and complex socioeconomics in the developing world, combating anemia is a global public health challenge.[7] Our study indicates that there is a high prevalence of anemia in school-going adolescent boys and girls. Adolescent health is the most important indicator of development of a nation. Hence, urgent attention is needed in this area. Evidence suggests that preventive supplementation coupled with nutrition education may be a more effective strategy associated with better compliance and improvement in iron status.[27] The result from our study indicates that the noniron Ayurvedic preparations *Sootshekhar Rasa* and *Sitopaladi Churana* can be used to improve the nutritional anemia status in adolescents without any side-effects. However, larger multicentric studies are required to assess the exact potential of the observed results.

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Disclosure Statement

No competing financial interests exist.

The *Sootshekhar Rasa* and *Sitopaladi Churana* combination has recently been granted a license from the authority of federal government of Uttarakhand, India and the drug is now commercially known as NUMAX.

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