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Study to Evaluate efficacy of *Vajravatakmandura* in Iron Deficiency Anemia in Adolescent Girls - A Randomized Controlled Trial

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ABSTRACT

Background: Anemia in adolescent girls possess greatest burden on their health as it leads to poor cognitive development, poor reproductive health and if not treated may lead to intrauterine growth retardation in their developing fetus. The prevalence of anemia among adolescent is 27% in developing country and 6% in developed country. By looking at the magnitude of the problem, an Ayurveda drug *Vajravatakmandura* has been selected for the study and the present study was undertaken to evaluate the efficacy of the trial drug in iron deficiency anemia in adolescent girls. **Material and methods:** 100 subjects satisfying inclusion and exclusion criteria were selected and were randomly divided in two groups. In group A, the trial drug *Vajravatakmaṇḍura* was administered and in group B, IFA tablets were given for two month of duration with follow up at every fortnight. **Result:** Both the trial and control groups showed extremely significant result over subjective parameters. Trial drug *Vajravatakmaṇḍura* in group A was found more effective over the subjective parameters - weakness, palpitation, pallor and loss of appetite with % gain of 39.77%, 39.39%, 39.17%, 38.09% respectively. Statistical analysis between before and after treatment findings of objective parameters, extremely significant ($P<0.0001$) improvement was found in both groups in all parameters, except for RBC count in group A, which was significant. No adverse effects were reported during entire period of study by any of the patients in trial group treated with trial drug. **Conclusion:** The trial drug *"Vajravatakmandura"* is effective, safe and palatable for the management of iron deficiency anemia in adolescent girls.

Key words: *Anemia, Adolescent Girls, Iron Deficiency, Pandu Roga, Ayurveda.*

INTRODUCTION

Anemia is a major public health problem worldwide and is often ignored in both developed and developing countries. Preschool children, pregnant women and adolescents constitute vulnerable group of anemia. Anemia may result in reduced growth and increased morbidity. Further, it causes important health and social and economic consequences, hampers cognitive development, reduce physical work capacity.

Adolescence is a vulnerable period in the human life cycle for the development of nutritional anemia which affects both sexes and all age group. Particularly in developing countries, among adolescents, girls constitute most vulnerable for anemia. Adolescence is the formative period of life where maximum amount of physical, psychological and behavioral change takes place.

The prevalence of anemia among adolescent is 27% in developing country and 6% in developed country.[1] A

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study which was conducted in the rural areas of Tamilnadu revealed that the prevalence of the anemia among the adolescent girls as 44.8%.[2] Another study, conducted among the girls, who belonged to the low income families in Lucknow, revealed that 67% of the adolescent girls were anemic.[3]

Anemia in adolescent girls possess greatest burden on their health as it leads to poor cognitive development, poor reproductive health and if not treated may lead to intrauterine growth retardation in their developing fetus. The Government of India has launched National Anemia Control Programme, to prevent and control anaemia in children and adolescents. Iron and folic acid (IFA) tablets are supplied free to all children, adolescents and pregnant mothers by means of dispensaries and ASHA workers. But the problem is still persisting because of many issues like - poor palatability, intolerance to the drug used, poor absorption of the drugs used, constipation, discoloration of stool, unpleasant odor etc. result in poor compliance and therefore non adherence to the therapy which finally results in poor improvement. Also the taste and side effects of presently available drugs are not suited to children and adolescence.

By looking at the magnitude of the problem greater efforts are needed to develop and implement program both to prevent and control anemia with a better and palatable drug with good taste and easy administration. In Ayurveda, symptoms of Iron deficiency anemia are described under *Pandu Roga*. In Ayurveda, a lot of different types of formulations are available for the management of *Pandu Roga* (anaemia). With this view, the present study entitled "A Study to Evaluate Efficacy of *Vajravatakmaṇḍura* in Iron Deficiency Anemia in Adolescent Girls: A Randomised Control Trial" was conducted.

OBJECTIVES OF THE STUDY

The present research work was undertaken with following main objectives:

1. To evaluate the clinical efficacy of an Ayurvedic compound "*Vajravatakmandura*" in the management of Iron Deficiency Anemia in adolescent girls.
2. To establish clinical safety of the study drug.

MATERIAL AND METHODS

- **Study type:** Randomized Controlled Trial
- **Masking:** Open label
- **Control:** Controlled (IFA Tablets)
- **Duration:** 8 weeks
- **End point:** Safety and Efficacy
- **No. of groups:** Two
- **Sample size:** 100

TIMELINES

- **Total trial period:** 8 weeks
- **Washout/Preparatory Period:** 4 weeks (if required)
- **Follow-Up period:** 4 weeks

Selection of Cases

Source:

Female subjects attending the O.P.D. and I.P.D. of Kaumarabhritya, PG Department of National Institute of Ayurveda, Jaipur and from various schools situated in Jaipur by survey method were screened for the present study.

Age Group

Adolescent girls of 12-15 years of age were selected for the study.

Grouping of patients

Total 100 cases will be divided into two groups (50 in each)

Group A: Trial drug (Vajravatakmandura) (50 cases)

Group B: Control (IFA Tablets) (50 cases)

Inclusion Criteria

1. Adolescent girls aged between 12-15years.
2. Adolescent girls with iron deficiency anemia (Hb 8g.-12g.%).

Exclusion criteria

1. Adolescent girls suffering from major systemic illness necessitating long term treatment.

ISSN: 2456-3110 ORIGINAL ARTICLE Jan-Feb 2018

2. Adolescent girls with evidence of malignancy.
3. Adolescent girls with concurrent serious hepatic dysfunction (defined as AST and/or ALT>3 times of the upper normal limit) or renal dysfunction (defined as S. creatinine>1.2mg/dl) uncontrolled pulmonary dysfunction (asthmatic and COPD subjects)
4. Co-morbidity like TB, UTI and bleeding disorders etc.
5. H/o hypersensitivity to any of the trial drug or their ingredients.
6. Adolescent girls who have completed participation in any other clinical trial during the past six months.

Assessment Criteria

For assessment of the efficacy of the trial therapy, following parameters were adopted-

- **Subjective:** Based on clinical features of anemia according to both modern and Ayurveda parameters on the basis of presenting features on four point scale.
- **Objective:** Laboratory findings were assessed before and after treatment. Hb%, CBC, PBS, Stool routine and microscopic.

Adverse effects

To rule out the possible adverse effects of the trial drug, record of information was maintained on every follow-up i.e. gastric irritation, gastric upset, constipation, diarrhoea, teeth discoloration, other untoward effect if any.

Study Drug : *Vajravatakmaṇḍura*[4]

Vajravatakmandura is an Ayurveda herbo-mineral formulation for the treatment of *Panduroga*. The trial drug *Vajravatakmaṇḍura* was prepared in the attached Pharmacy of the institute. The compound was modified to make it in tablet form for easy administration to adolescent girls. *Takra* (butter milk) as mentioned in original text was taken as vehicle of the trial drug. (Schedule of the treatment is as shown in Table 1)

Table 1: Showing schedule of the treatment

	Group A (n=50)	Group B (n=50)
	Trial drug (*Vajravatakmaṇḍura*)	Control drug (IFA tablets)
Dose	500mg in two divided doses	100 mg elemental iron and 500 mcg folic acid
Dosage form	Tablet	Tablet
Route	Oral (After meals)	Oral (After meals)
Anupana	Butter milk	Water
Duration	8 weeks	8 weeks

IEC Approval

Institutional Ethics committee's approval was taken to conduct the clinical trial. Study was approved by IEC, National Institute of Ayurveda, Jaipur, and order no. -F10 (5)/EC/2014 /7220. A voluntary signed, witnessed informed consent was obtained from the participant / parents/ guardians prior to the start of clinical trial.

The trial was also registered in CTRI with registration number CTRI/2017/10/010037.

OBSERVATIONS

In present study, loss of appetite, improper digestion, pallor were commonly observed premonitory symptoms, while falling of hairs, weakness in feet, lack of interest in routine activities were most commonly observed symptoms. While in demographic study fatigue was most prevalent symptom which was observed during the survey. (Table 2)

Table 2: Showing common observations of clinical study

Factor	Classification	Group A (n=50)		Group B (n=50)		Total	
		No	%	No	%	No	%
Severity of	Mild (Hb<12-	36	72	38	76	74	74

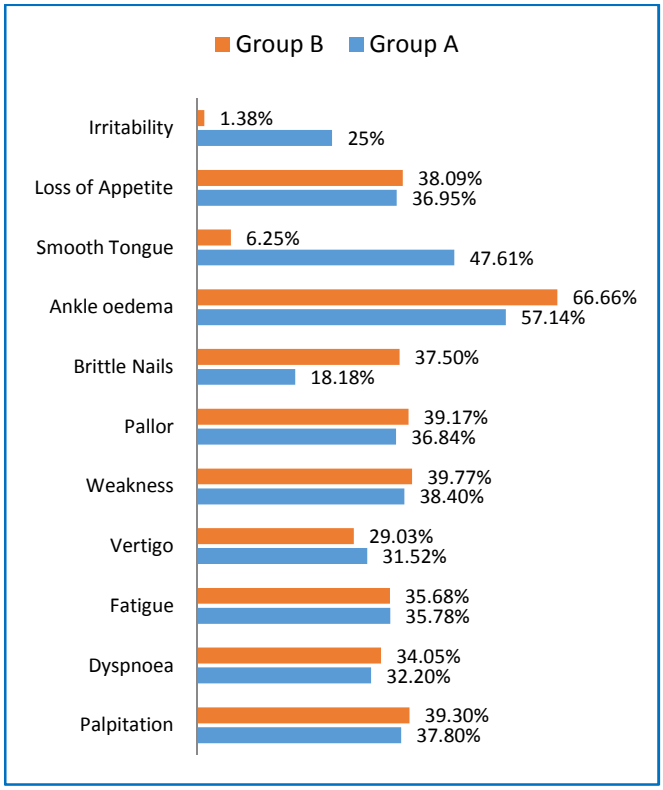
ISSN: 2456-3110 **ORIGINAL ARTICLE** Jan-Feb 2018

Anemia	10%)						
	Moderate (Hb <10-8%)	09	18	08	16	17	17
	Severe (Hb<8%)	05	10	04	08	09	09
Age Group (in years)	12 to <13	13	26	15	30	28	28
	13 to <14	18	36	17	34	35	35
	14 to <15	19	38	18	36	37	37
Menarche	Achieved	32	64	28	56	60	60
	Not achieved	18	36	22	44	40	40
Religion	Hindu	22	44	30	60	52	52
	Muslim	28	56	20	40	48	48
	Others	00	00	00	00	00	00
Habitat	Urban Area	44	88	48	96	92	92
	Rural Area	06	12	02	04	08	08
Economic status	Higher	00	00	01	01	01	01
	Upper Middle	10	20	07	14	17	17
	Lower Middle	26	52	31	62	57	57
	Lower	14	28	11	22	25	25
Immunization Status	No immunization	11	22	14	28	25	25
	Incomplete	08	16	06	12	14	14
	Complete	10	20	07	14	17	17
	Unknown	21	42	23	46	44	44
Diet	Vegetarian	20	40	22	44	42	42
	Mixed	30	60	28	56	58	58
Weight	Average	32	64	30	60	62	62
	Under weight	18	36	19	38	37	37
	Over weight	00	00	01	02	01	01
Hygienic Condition	Good	14	28	09	18	23	23
	Moderate	30	60	27	54	57	57
	Poor	06	12	14	28	20	20
Sleep	Sound	32	64	26	52	58	58
	Disturbed	22	44	20	40	42	42
Appetite	Poor	35	70	42	84	77	77
	Good	15	30	06	12	21	21
	Excessive	00	00	02	04	02	02

RESULTS

Both the trial and control groups showed extremely significant result over subjective parameters. Trial drug *Vajravatakmaṇḍura*in group A was found more effective over the subjective parameters - weakness, palpitation, pallor and loss of appetite with % gain of 39.77%, 39.39%, 39.17%, 38.09% respectively. (Figure 1)

Figure 1: Effect of therapy on Subjective Parameters



ISSN: 2456-3110 ORIGINAL ARTICLE Jan-Feb 2018

Statistical analysis between before and after treatment findings of objective parameters, extremely significant (P<0.0001) improvement was found in both groups in all parameters, except for RBC count in group A, which was significant with P value 0.0248. (Table 3)

Table 3: Showing pattern of Hematological changes in cases of IDA in Group A and in Group B (Paired't' test)

Features	Group	Mean			SD	SE	P	IPT
		BT	AT	Diff				
Hemoglobin	A	11.04	12.14	1.094	0.65	0.92	<0.0001	ES
	B	10.11	11.25	1.114	0.51	0.07	<0.0001	ES
RBC	A	4.277	4.657	0.379	1.15	0.16	0.0248	S
	B	4.033	4.517	0.484	0.29	0.04	<0.0001	ES
PCV	A	27.50	37.28	9.788	2.01	0.28	<0.0001	ES
	B	27.83	36.88	9.050	2.95	0.41	<0.0001	ES
MCV	A	68.57	78.09	9.516	3.33	0.47	<0.0001	ES
	B	66.38	75.95	9.564	3.53	0.50	<0.0001	ES
MCH	A	25.53	28.23	2.700	1.24	0.17	<0.0001	ES
	B	24.61	27.60	2.988	1.27	0.18	<0.0001	ES
MCHC	B	32.56	34.87	2.308	1.98	0.28	<0.0001	ES
		32.59	34.15	1.552	1.36	0.19	<0.0001	ES

No unpleasant outcome of the trial drug was observed throughout the study.

DISCUSSION

Total 122 subjects were enrolled out of which 22 subjects dropped out. Study was conducted on 100 subjects. In both control group (Iron and Folic acid) and trial group (*Vajravatakmaṇdura*) 50 subjects in each group completed the course of treatment.

It was found that majority of subjects 74 (74%) were of mild anemia (Hb <11.5-10%). The prevalence among adolescent girls is well supported by previous studies.[5] This study shows that mild variety of anemia is more prevalent among adolescent girls. Only 9 (9%) subjects were having severe anemia (Hb<8%). In these subjects with severe type of anemia other associated features were more prevalent and most of the subjects provided history of heavy bleeding during menstrual cycle.

Thus, there no strong association of anemia was observed with menarche in the present study. Few studies reported no association between status of menarche and anemia which supports the present findings.[6]

There was no any significant difference seen between different age groups because the age group range was very small. But it was observed that anemia was more prevalent in adolescent girls aged between 14 to 15 years. Studies also document that age is not a correlated factor.[7-10]

Adolescent girls are particularly prone to iron deficiency anemia because of increased demand of iron for hemoglobin, myoglobin and to make up the loss of iron due to menstruation and poor dietary habits.[11]

The trial drug (*Vajravatakmaṇdura*[12]) possesses antioxidant, anti-inflammatory, bio-availability enhancing, anti-inflammatory, anti-helminthic properties and above all *Mandura Bhasma* which is a good hematinic, due to which extremely significant improvement was observed. (Table 4)

ISSN: 2456-3110 ORIGINAL ARTICLE Jan-Feb 2018

Table 4: Showing properties of ingredients of Trial Drug (*Vajravatakmandura*)

Drugs	Effect
Piper longum	Anti-oxidant activity[13] Anti-inflammatory activity.[14]
Piper longum	Anti-oxidant activity[15] Anti-inflammatory activity.[16]
Piper chaba	Gastroprotective and cholesterol lowering properties,[17] Antioxidant activities[18]
Plumbago zeylanicum	Antidiarrheal activity.[19] Antibacterial activity[20]
Zingiberofficinale	Anti-inflammatory, antitumour and antioxidant activities of ginger[21] Anti- parasitic effect (L. nilotica)[22]
Piper nigrum	Anti-inflammation.[23] Bio-availability enhancing [24]
Cedrusdeodara	Anti-inflammatory[25] Antibacterial action[26]
Terminalia chebula	Antioxidant and radical scavenging abilities, compared to the standards.[27] Cytoprotective and antiaging activities[28]
Terminalia bellarica	Antioxidant and radical scavenging abilities[29]
Emblica officinalis	Antioxidant and radical scavenging abilities[30] Anti- ageing effects[31]
Embelia ribes	Antioxidant property[32] Anthelmintic activity[33]
Cyperus rotundus	Improving the small intestine absorption[34] Hepatoprotective activity against CCl4 induced activity[35]
Mandura (Fe_2O_3)	Hematinic [36]

CONCLUSION

Nutritional anaemia is a major public health problem in India and is primarily due to iron deficiency especially in girls where they are exposed to risk of onset of menarche. Trial drug *Vajravatakmaṇdura* showed almost equal and extremely significant improvement as compared to control drug IFA tablets. However *Vajravatakmaṇdura* showed better results on all cardinal features except vertigo and irritability. Extremely significant improvement was observed in all objective parameters in both groups, except for RBC count in group A in which only significant improvement was found. In intergroup comparison all subjective and objective parameters showed non-significant result. No adverse effects were reported during entire period of study by any of the patients in trial group treated with *Vajravatakmaṇdura.* The trial drug *Vajravatakmandoor* is effective, safe and palatable for the management of iron deficiency anemia in adolescent girls.

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ISSN: 2456-3110 **ORIGINAL ARTICLE** Jan-Feb 2018

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