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Research Article

A CLINICAL STUDY TO DETERMINE THE ROLE OF *GUDA HARITAKI* AND *PUNARNAVA MANDURA* IN THE MANAGEMENT OF *PANDU ROGA* W.S.R. TO IRON DEFICIENCY ANAEMIA AMONG CHILDREN

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ABSTRACT

Nutritional anaemia is frequently observed in India. Prevalence of anaemia in Indian children is 59% (Hb<11gm/dl) but it's higher among rural children. Iron deficiency is most common type nutritional deficiency anaemia in children. The nearest correlation of iron deficiency anemia (IDA) can be made with *Pandu Roga* in Ayurveda. The side effects of oral allopathic iron preparations are very common, therefore to get a better alternative, two Ayurvedic medicines, the *Guda Haritaki* and *Punarnava Mandura*, were subjected to a clinical trial among children suffering from IDA. **Aim:** Determine the role of *Guda Haritaki* and *Punarnava Mandura* in the management of *Pandu roga* w.s.r. to iron deficiency anaemia among children. **Materials and Methods:** The study was conducted on 35 children of IDA for a period of 6 weeks. Clinical features (*Panduta, Daurbalya* etc.) and hematological parameters (Hb gm %, sr. ferritin etc.) were documented before, during and after treatment. **Statistical Analysis Used:** Observations of the study were analyzed and findings were evaluated by using statistical methods **Results:** In the present study 58.82% improvement in *Panduta* was observed with *Guda haritaki,* 65% with *Punarnava Mandura* and 67 % when both drugs were given together. No adverse effect of the trial drug was observed during the study. **Conclusions:** The results suggest that *Punarnava mandura* along with *Guda Haritaki* is more effective in comparison to single use of either formulation in the management of IDA in children.

KEYWORDS: Anemia, hemoglobin, Iron deficiency, *Pandu Roga*, Serum ferritin.

INTRODUCTION

The clinical features like pallor, anorexia, irritability and pica etc clinically manifest Iron deficiency anaemia. Iron deficiency anaemia is affecting nearly 2 billion people globally i.e. around 1/3 of the whole population [1].In India, iron deficiency is responsible in about 50% of anaemic cases. Adolescents constitute more than 20% of Indian population and more than 50% of them suffer from iron deficiency anemia[2]. NFHS 2015-16 suggests that prevalence of anaemia in Indian children is 59% (Hb<11gm/dl) but it's higher among rural children. Nutritional iron deficiency is the most common cause of anemia in India.[3] The features of iron deficiency anaemia are almost similar with that of *Pandu Roga* mentioned in Ayurvedic classics. The ancient system of medicine has described *Pandu* (disease of pallor) which includes various types of anaemia. IDA is a very common disease prevalent in the society and side effects of oral allopathic iron preparations are very frequently encountered.[4] There are about 200 preparations are quotated in various ayurvedic texts for management of *Pandu Roga*. With the aim that Ayurvedic medicines may be effective to manage childhood IDA without any side effects, the present study was carried out to study the efficacy of an Ayurvedic herbomineral compound *Guda Haritaki* and *Punarnava Mandura* with the application of modern parameters like hemoglobin conc., serum ferritin value and MCV, MCHC etc.

AIMS AND OBJECTIVES

Primary objective: To assess the clinical efficacy of *Punarnava Mandura* and *Guda Haritaki* in the management of iron deficiency anaemia among children.

Secondary objective: To assess the clinical safety of *Punarnava Mandura* and *Guda Haritaki* in the patients of iron deficiency anaemia.

Plan of Study

Conceptual study: Ayurvedic and modern literature pertaining to iron deficiency anaemia was critically reviewed.

Clinical study: This was the main part of the present research work. A sample of 35 patients was assessed during the trial.

The registered study subjects were randomly divided in three groups.

Group A: 15 Patients – *Guda Haritaki* 500mg/kg/day, before meal (divided in two doses)

Group B: 10 patients – *Punarnava Mandura* 500 mg twice a day, before meal

Group C: 10 Patients – Each patient was managed as follows.

1. *Guda Haritaki* 500mg/kg/day, before meal (divided in two doses)
2. *Punarnava Mandura* 500 mg twice a day, before meal

Protocol of Research

1. **Consent:** A voluntary, signed, witnessed consent was obtained from the participants/ parents/ guardians prior to the clinical study.
2. **Selections of the patients:** Patients were randomly selected from OPD and IPD of R.G.G. P.G. Ayurvedic College and Hospital Paprola district Kangra (H.P.)
3. **Diagnosis of patients:** A detailed history was taken and complete physical examination, laboratory investigations were carried out based on both Ayurvedic as well as modern system of medicine to confirm the diagnosis of iron deficiency anaemia.

Inclusion Criteria

1. Children of either sex aged between 10-16 years.
2. Children with iron deficiency anaemia having Hb levels between 7-11 gm%.
3. Patients willing and able to participate for 6 weeks duration.

Exclusion Criteria

1. Children having Hb levels < 7gm% or >11 gm%.
2. Children suffering from major systemic illness necessitating long term drug treatment.
3. Children having co- morbidities like tuberculosis, chronic urinary tract infection, bleeding disorders etc.
4. History of hypersensitivity to any of the trial drug or their ingredients.
5. Children who have participated in any other clinical trial during the past six months.
6. Any other condition which the Principal investigator thinks may jeopardize the study.

Criteria for Withdrawal

1. Patients non complaint to treatment regimen.
2. Patient himself /herself wants to withdrawn from trial.
3. Patients who will develop any other co-morbidity during trial period which require immediate pharmacological intervention.
4. Adverse drug reaction to trial drug.

Methods of Sampling

Direct sampling, double arm study (Randomized Clinical Trial) was followed.

Selection of the Drug

In the classical texts, many preparations have been mentioned for the treatment of *Pandu roga*, out of which for the present study as a trial drug a herbomineral compound "*Punarnava Mandura*"[5] and *Guda Haritaki*" [6] have been selected which is mentioned in the Ayurvedic classic *Charaka Samhita* and *Sushruta Samhita-Panduroga chikitsadhyaya*.

Selection of Drug Form

As quoted by *Charakacharya* that the drugs to be administered in *Baala* should have *Madhura, Kashaya Rasa*. After various pilot studies the *Avaleha* dosage form was found to be more acceptable and hence *Avaleha* form has been selected for the present study.

Approval of Institutional Ethical Committee

Institutional Ethics committee's approval was taken for the prospective, randomized parallel group clinical study.

Procurement of the Drug

Guda Haritaki was prepared in the attached Charaka pharmacy of the institute. The trial drug *Punarnava Mandura* is prepared by K.L.E. Ayurveda Pharmacy, Upper Galli-Khasbag, Belgavi-4. All concerned drugs are taken in mentioned proportion in text and made in to *Vati* form of 250 mg each.

Contents of the Trial Drugs

Contents of *Guda Haritaki* and *Punaranava Mandura* are presented in Table 1 and Table no. 2 respectively.

Table 1: Ingredients of *Guda Haritaki*

S.no.	Name	Botanical /English name	Family	Part used
1	*Haritaki*	*Terminalia chebula*	Combretaceae	Pericarp
2	*Guda*	Jaggerry	--	-
3	*Madhu*	Honey	-	-

Table 2: Ingredients of *Punarnava Mandura*

Sr.No.	Name	Botanical name	Family	Part used
1.	*Punarnava*	*Boerhaavia diffusa* Linn.	Nyctaginaceae	Root
2.	*Mustaka*	*Cyperus rotundus*Linn.	Cyperaceae	Rhizome
3.	*Trivrita*	*Operculina turpethum* Linn.	Convulvulaceae	Root
4.	*Vyosha*	*Zingiber officinalis* Roxb.	Zingeberaceae	Rhizome
5.	*Vidanga*	*Embelia ribes* Burm.F.	Myrsinaceae	Fruit
6.	*Daruharidra*	*Berberis aristata* DC.	Berberidaceae	Bark
7.	*Chitraka*	*Plumbago zeylanica* Linn.	Plumbaginaceae	Root
8.	*Kustha*	*Saussurea lappa* CB. Clarke.	Compositae	Root
9.	*Haridra*	*Curcuma longa* Linn.	Zingeberaceae	Rhizome
10.	*Haritaki*	*Terminalia chebula* Retz.	Combretaceae	Pericarp
11.	*Bibhitaki*	*Terminalia bellirica*	Combretaceae	Pericarp
12.	*Amalaki*	*Embelica officinalis* Gaertn.	Euphobiaceae	Pericarp
13	*Danti*	*Baliospermum montanum*	Euphobiaceae	Root
14.	*Chavya*	*Piper retrofactum* Vahl.	Piperaceae	Root
15.	*Kalingaka*	*Holarrhena antidysenterica* Wall.	Apocynaceae	Seed
16.	*Pippali*	*Piper longum* Linn.	Piperaceae	Fruit
17.	*Pippalimool*	*Piper longum* Linn.	Piperaceae	Root
18.	*Mandura Bhasma*	Iron oxide Calx	*Dhatu Varga*	-
19.	*Go-Mutra*	Cow Urine	-	-

Analytical Study of Trial Drug

The trial drug sample was subjected to various physiochemical analytical tests to evaluate the standards of drug.

Analytical test reports of the trial drug *Guda haritaki* are as follows.

Nature of preparation: Viscous liquid

Colour: Dark brow

Odour: Characteristics

Taste: Sweet and astringent

pH: 3.65

Refractive index: 1.505 at 24^0c

Predicted shelf life (ASLT): 3 years from manufacturing date

The sample exhibited positive test for tannins.

Analytical test reports of the trial drug *Punarnava mandura* are as follows

Nature of preparation: *Vati*

Colour: Blackish Brown

Odour: Characteristic

Taste: Slightly bitt

Ash value: 56.348%

Acid insoluble ash: 5.642%

Predicted shelf life (ASLT): 6 years from manufacturing date

Microbial contamination tests, heavy metal residues, and pesticide residues were within the normal limits. The sample exhibited positive test for iron.

Schedule of Treatment

Deworming was done before drug therapy in suspected cases.

The registered study subjects were randomly divided in three groups.

Group A: 15 Patients – *Guda haritaki* 500mg/kg/day, before meal (divided in two doses)

Group B: 10 patients – *Punarnava mandura* 500 mg twice a day, before meal

Group C: 10 Patients – Each patient was managed with both drugs in similar doses.

Duration of treatment: 4 weeks.

Diet: Normal diet was advised to all the cases according to age.

Follow-ups were done every 2 weeks.

Follow-up feedback (responses on treatment) were taken after 6weeks

Assessment Criteria

The results of the clinical study were assessed on the basis of observations of clinical features and laboratory findings. The following parameters were mainly adopted for assessing the response of the treatment.

Clinical Assessment: *Vaivarnata* (pallor), *Daurbalya* (weakness), *Shrama* (fatigue), *Aruchi* (anorexia), *Kopana* or *Adhira* (irritability), *Shwasa* (dyspnea), *Hridayaspandana* (palpitation) etc clinical findings were assessed before, during, and after the treatment.

Panduta (Twacha, Nakha, Netra, Jihwa, Hastapadana **(Pallor)**

Absent	:	0
Present at 1 sites	:	1
Present at 2 sites	:	2
Present at 3 sites	:	3
Present at all sites	:	4

Daurbalya **(Weakness)**

Not present	:	0
After heavy work, relieved soon and tolerable	:	1
After moderate work, relieved soon and tolerable	:	2
After little work, relieved later and tolerable	:	3
After little work, relieved later and beyond tolerable	:	4

Hridaspandanama **(Palpitation)**

Not present	:	0
After heavy work, relieved soon and tolerable	:	1
After moderate work, relieved soon and tolerable	:	2
After little work, relieved later and tolerable	:	3
After little work, relieved later and beyond tolerable	:	4

Shunakshikuta (**Periorbital edema*****)***

Absent	:	0
Mild	:	1
Moderate	:	2
Severe	:	3

Aruchi **(Anorexia)**

Absent	:	0
Present	:	1

Pindikodwestana **(Calf muscle pain)**

Absent	:	0
After heavy work	:	1
After moderate work	:	2
Without work	:	3

Ayasaja swasa **(Shortness of breath)**

No	:	0
Mild	:	1
Moderate	:	2
Severe	:	3
Very severe	:	4

Shirshoola **(Headache)**

No	:	0
Mild	:	1
Moderate	:	2
Severe	:	3
Very severe	:	4

Bhrama **(Dizziness)**

No	:	0
Mild	:	1
Moderate	:	2
Severe	:	3

Mukha paka **(Angular stomatitis)**

Not present	:	0
Present occasionally	:	1
Present mostly	:	2

Karnakshweda **(Tinnitus)**

Not present	:	0
Present occasionally	:	1
Present mostly	;	2

Pica

Not present	:	0
Present	:	1

Disturbed sleep

Not present	:	0
Present	:	1

Laboratory Investigations

1. Hb (Haemoglobin)
2. Total RBC (Red Blood Cell)
3. Total WBC (White Blood Cell)
4. PCV (Pack Cell Volume)
5. MCV (Mean Corpuscular Volume)
6. MCH (Mean Corpuscular Haemoglobin)
7. MCHC (Mean Corpuscular Haemoglobin Concentration)
8. ESR (Erythrocyte Sedimentation Rate)

Biochemical examination: Blood sugar, SGOT, SGPT, Blood Urea, Sr. Creatinine, Sr. Ferritin

Criteria of Assessing Overall Effect of Therapy

The assessment of overall effect was done after completion of treatment i.e. after 4 weeks.

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Table 3: Criteria of assessment of effect of therapy

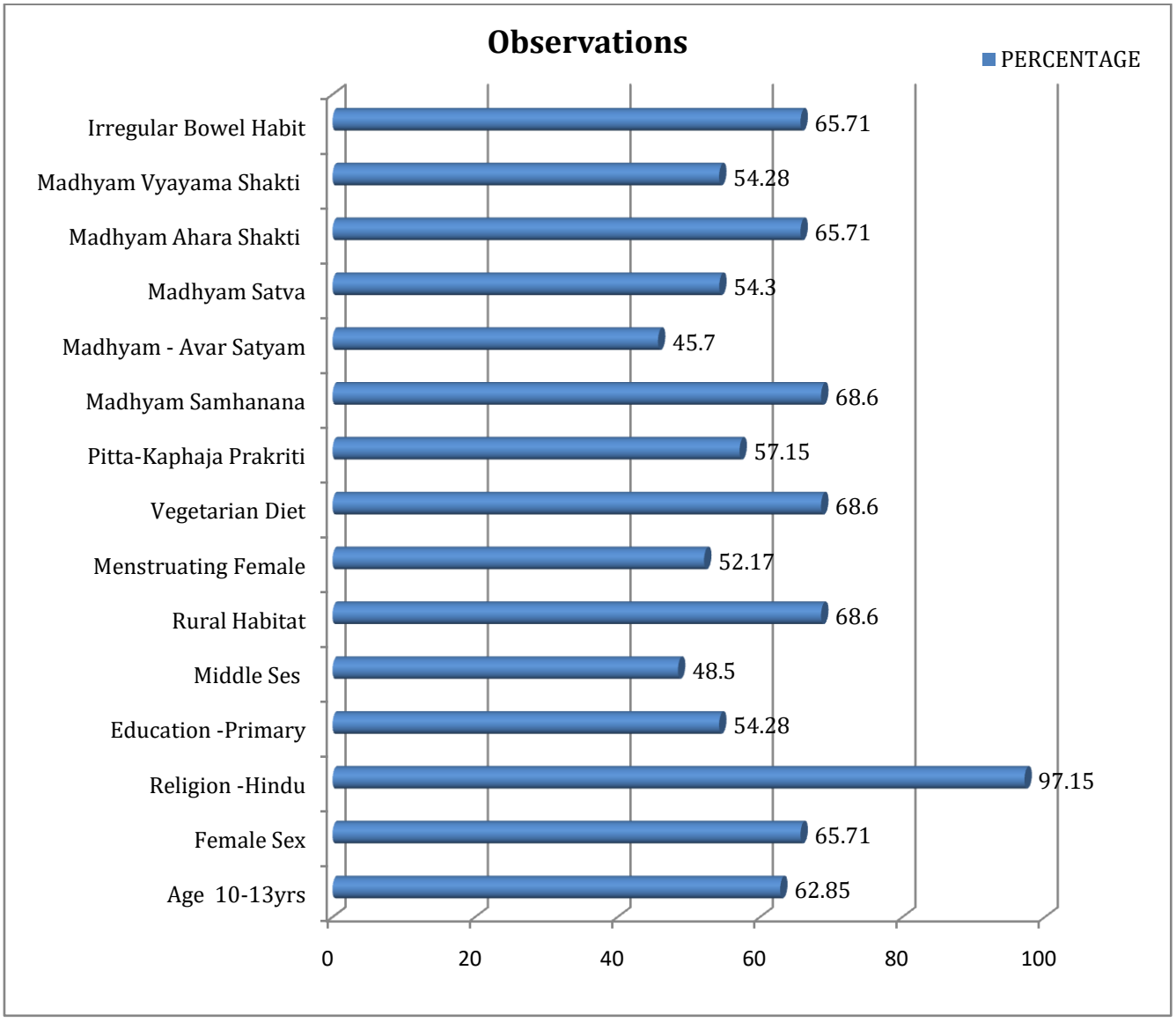
Cure	100% in the subjective parameter
Markedly Improvement	>75% improvement in the subjective parameter
Moderate Improvement	50 to 74% improvement in the subjective parameter
Mild Improvement	25 to 49% improvement in the subjective parameter
Unchanged	<25% improvement in the subjective parameter

Statistical Analysis: The result obtained from the study were subjected to statistical analysis in term of mean, standard deviation (S.D.) and standard error (S.E.), t value, p value and f values in paired 't' test and Anova test was carried out at p> 0.05, p< 0.05, p< 0.01, p< 0.001 and a significant level for each set of data. The obtained results were interpretated as Insignificant (p> 0.05), Significant (p< 0.05, p<0.01) and highly significant (p< 0.001).

Observations and Results

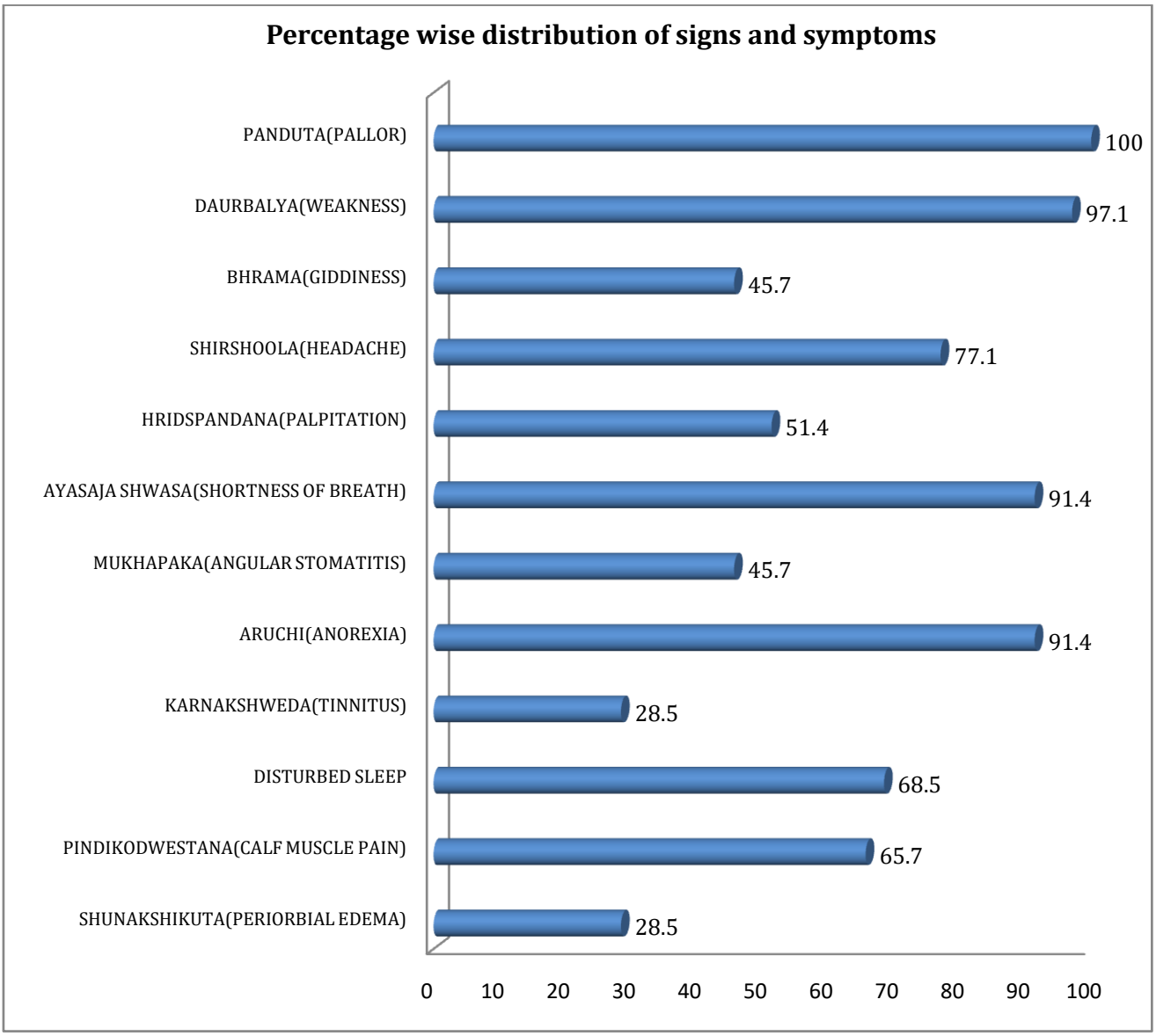
In the present study 60 children were screened, out of which 35 children were registered and 29 patients has completed the trial. 6 patients were dropout from the trial.

Figure 1: Observations



Majority of patients (62.85%) were in the age group of 10-13 years. Maximum number of patients i.e., 65.71% were female followed by 34.29% were male. Most of the registered subjects were educated up to primary (54.28%) and 35.71% patients were studying in high school. The maximum numbers of patients (48.50%) were from middle class, followed by (42.85%) patients of lower middle class and patients of upper class were least in number (8.65%). In present study 68.60% patients were dwelling in rural area followed by 31.40% in semi-urban area and none of the patient was from urban area. This study shows (52.17%) of patients were of menstruating age group and (47.83%) patients were of non menstruating age group. A total of 68.60% of patients were vegetarian and 31.40% patients were mixed types and none of the patients were non-vegetarian. Maximum number (57.15%) patients were of *Pittakapha prakriti* type followed by 28.55% were *Vatapitta prakriti* type and 14.25% were *Vatakapha prakriti*. In this study maximum (65.71%) patients of iron deficiency anemia had regular bowel habit followed by 37.29% patients having irregular bowel habit.

Figure 2: Presentation of symtomatological data



All patients (100%) had pallor followed by weakness (97.1%), shortness of breath and anorexia each (91.4%), headache (77.1%), disturbed sleep (68.5%) patients were having, calf muscles pain (65.7%), palpitation (51.4%), giddiness and angular stomatitis each (45.7%), tinnitus and periorbital edema (28.5%) and 22.8% patients had pica.

DISCUSSION

Table 4: Effect of therapy (A)

Subjective Parameters	Mean score			% Relief (Improvement)			SSC	MSC	F value	P value	Result
	Df_a	Df_b	Df_c	Df_a	Df_b	Df_c					
	n = 10	n = 9	n = 10	n = 10	n = 9	n = 10					
Panduta	1.000	1.111	1.300	58.82	67	65	7.448	0.266	1.128	0.347	IS
Daurbalya	0.900	0.778	1.400	40	58.28	69.6	6.966	0.249	5.013	0.019	S
Bhrama	0.500	0.556	0.800	62.50	71.4	88.9	10.828	0.387	0.745	0.489	IS
Shirshoola	0.700	0.444	1.000	53.84	50	71.42	7.793	0.278	2.902	0.082	IS
Hridspandana	0.500	0.889	1.100	55.57	61.5	78.6	14.138	0.505	2.559	0.107	S
Ayasaja shwasa	0.800	0.556	1.300	66.67	55.6	76.5	14.69	0.525	3.075	0.072	IS
Pica	0.200	0.222	0.100	66.67	100	50	4.138	0.148	0.224	0.802	IS
Mukhapaka	0.400	0.333	0.800	66.67	75	89	13.241	0.473	1.1358	0.284	IS
Aruchi	0.800	0.667	0.800	80	100	80	5.310	0.190	0.386	0.685	IS
Karnakshweda	0.100	0.222	0.300	50	66.7	100	4.759	0.170	0.630	0.545	IS
Brittle nails	0.100	0.222	0.100	25	100	20	3.448	0.123	0.327	0.726	IS
Disturbed sleep	0.500	0.556	0.600	71.42	71	86	7.172	0.256	0.112	0.894	IS
Pindikodwesta	0.300	0.788	1.000	60	64	77	12.207	0.436	4.621	0.025	S
Shunakshikuta	0.100	0.333	0.300	100	50	100	5.310	0.190	0.889	0.425	IS

In the present study 58.82% improvement in *Panduta* was observed with *Guda haritaki,* 65% with *Punarnava mandura* and 67 % when both drugs were given together. Result was found statistically highly significant in all three groups (p<0.001). *Guda haritaki* contains *Haritaki* which is *Yakritutejaka* [7] hence, potential to regularize *Moola* of *Raktavaha srotasa* which ultimately helps in improving the process of *Rakta* formation. It also contains *Guda* and *Madhu* which are rich source of iron. It also pacifies vitiated *Pitta dosha*, thus overcomes *Panduta*. Intergroup comparison on *Panduta* then was statistically insignificant (P value=0.347, F value =1.128).

Daurbalya was present in 97 % patients just like previous studies.[17] It is caused due to *Ojaskshaya, Dhatu kshaya* and *Raktalpata.*[8] Statistically highly significant improvement (p value <0.001) in *Daurbalya* was observed in three groups with 40%, 58.28% and 69.60% improvement in group A, B and C respectively. *Punarnava mandura* contains *Triphala* which has *Rasayana* property while *Guda haritaki* contains *Haritaki* which also has *Rasayana* Property so it is effective in decreasing *Daurbalyata*[8]. It was observed that there was statistically significant difference (p=0.019) among the groups. However therapy given in group-B had little upper edge over group-A and group-C was found most effective in managing *Daurbalya*.

Hridaspandana or palpitation occurs as a compensatory mechanism in the body, as due to lack of RBC in blood oxygen transport has to be compensated by increased blood flow to the peripheral circulation. This can be done by increased heart rate by increasing the pumping blood[9]. Thus palpitation felt in the patients. It can be found due to *Vata Vridhi*. Among the 51.40% cases in which the symptom was observed, 55.57% relief was found in group A, 61.5% relief was found in group B and 78.6% relief was found in group C. It is significant result in all groups. There was significant difference (P=0.107) among three groups. However therapy given in group-B had little upper edge over group-A and group-C proved best in managing *Hrida-spandana. Guda Haritaki* contains *Haritaki*, which possess *Tridoshashamaka* property especially *Vatashamaka* along with *Raktavardhaka* properties of *Madhu* and *Guda.* So it might be the reason in decreasing *Hridaspandana*. *Punarnava Mandura* contains *Mandura which* is *Raktavardhaka* so helps to increase oxygen carrying capacity by improving haemoglobin thus workload on heart decreases.

Shunakshikuta was observed in only 28% patients. In group A and C 80% relief was observed. Such type of result may be due to *Guda haritaki* and *Punarnava mandura* which contain sufficient amount of iron and have potential to increase haemoglobin. A statistically insignificant improvement in *Shunakshikuta* was observed in all three groups i.e. group A (0.343), group B (0.081) and group C (0.081). Percentage improvement on *Shunakshikuta* in patients of group A, group B and group C was 80%,

50% and 80% respectively. The inter group comparison revealed that there was insignificant difference (P=0.425) among three groups. However therapy given in group-A and group-C proved equally affected but group-B proved least effective in managing *Shunakshikuta.*

Dyspnoea on exertion or *Ayasaja shwasa* in *Pandu* is due to *Raktalpata* which results in respiratory system to work quickly so as to provide rapid blood flow to body tissues.[10] *Shwasa* was found in 91.40% patients. Relief in *Shwasa* was maximum in group C i.e. 76.50% and in group A it was 66.67%. *Punarnava Mandura* using patients were relieved about 55%. There was insignificant difference (P=0.072) among three groups. *Guda Haritaki* contains *Guda* and *Haritaki* they both have *Deepana, Pachana* properties thus helps to improve *Agni* and ultimately helps in providing proper nourishment to the body. *Haritaki* is *Srotoshodhaka* so it opens the channels in intestine so that nutrients are absorbed properly. While *Punarnava mandura* contains *Pippali*, *Pippalimula*, *Chitraka* and *Shunthi* etc. which are known drug for their *Shwasahara* and *Kaphavata nashana* properties, It get quickly absorbed in *Shrotasa*. Both the drugs also increased Hb levels due to *Madhu, Guda* and *Lauha Bhasma* so oxygen carrying capacity of RBCs may be increased.

Aruchi was found in 92.50% registered patients. In *Pandu roga, Rasavaha srotodushti* is seen and *Aruchi* has been mentioned as *Rasavaha srotasa dushti lakshana* by *Acharya Charaka*. A statistically highly significant (p<0.001) improvement in *Aruchi* was observed in group A and group C while significant result in group B (P=0.004). Percentage improvement on *Aruchi* in patients of group A, group B and group C was 100%, 80% and 100% respectively. However therapy given in group-A and group-C had equal improvement but group-B proved best in managing *Aruchi.*

Pindikodwestana was seen in 61% of patients. A statistically significant improvement in *Pindikodwestana* was observed in group B (P=0.008) and group C (P=0.001). Percentage improvement on *Pindikodwestana* in patients of group A, group B and group C was 60%, 64% and 77% respectively. The inter group comparison revealed that there was significant difference (P=0.025) among three groups. However therapy given in group-B had little upper edge over group-A and group-C proved best in managing *Pindikodwestana.* In both formulations, drugs contain *Deepana* and *Pachana* property which helps in *Ama paachana*. Lactic acid can be considered as *Ama*. So that patient gets relieved from leg cramps. *Haritaki* is *Srotoshodhaka* and *Rasayana* so gives strength to the muscles. *Punarnava Mandura* have *Triphala* which is *Rasayana* thus gives strength to muscles.

Disturbed sleep was seen in 68.5% patients. A statistically significant improvement in disturbed sleep was observed in all three groups i.e. group A (0.015), group B (0.013) and group C (0.005) with 71.42%, 71% and 86% improvement respectively. An insignificant difference (P=0.894) among three groups where therapy given in group-A had little upper edge over group-B and group-C proved best in managing disturbed sleep.

Headache was present in 71.10% patients. Previous researchers also reported the similar observations.[17] A statistically highly significant (p<0.001) improvement in *Shirshoola* was observed in groups i.e. group C while significant improvement was observed in group B (P=0.001) and group A (P=0.035). Percentage improvement on *Shirshoola* in patients of group A, group B and group C was 50%, 53.84% and 71.42% respectively. The inter group comparison revealed that there was insignificant difference (P=0.082) among three groups. However therapy given in group-A had little upper edge over group-B and group-C proved best in managing *Shirshoola.*

Several studies showed that the milder form of anaemia is silent i.e. without symptoms, while in the severe cases it is associated with fatigue, weakness, dizziness and drowsiness.[14] This symptom is found in 45.70% patients only. 62.50 % relief in group A, 71.4% relief in group C while 88.9 % relief was found in group C. it was statistically significant result. Comparative result (F Value0.745 and p value 0.489) among groups is found statistically insignificant. In present study *Mukhapaaka* was found in 45% registered patients. It is a feature of long standing anaemia. Angular cheilitis is an inflammatory condition characterized by erosive inflammation at one or both angles of the mouth. It typically presents as erythema, scaling, fissuring, and ulceration. Effect of therapy was found significant in group A (p value 0.037), insignificant in group B (p value 0.195) and significant in group C with p value 0.011. 66.67% relief in group A, 75 % relief in group C while 89 % relief was found in group C. In comparison among the groups result was statistically insignificant with p value 0.284 and f value 1.1358. A wide variety of factors, including nutritional deficiencies, local and systemic factors, and drug side effects, may produce cheilitis/ glossitis.[11-12] Ringing in ears was found only in 28.50 % patients.

Iron is required for normal functioning of the auditory system. The loss of hemoglobin in red blood cells which carry oxygen to the tissues in the body.

Iron deficiency can disrupt the workings of cells and even kill them leading to hearing loss if that happens to hair cells in the inner ear[13] Iron deficiency results in the degradation of lipid saturase and desaturase, impairing energy production, and consequently, myelin production. Damage to the myelin surrounding the auditory nerve impairs conduction velocity resulting in noise induced hearing loss.[15]A statistically insignificant (p>0.1) improvement in *Karnakshweda* was observed in all three groups i.e. group A (P=0.343), group B (0.169) and group C (P=0.081). Percentage improvement on *Karnakshweda* in patients of group A, group B and group C was 50%, 66.7% and 81% respectively. The inter group comparison revealed that there was insignificant difference (P=0.545) among three groups. However therapy given in group-A had little upper edge over group-B and group-C proved best in managing *Karnakshweda.*

Pica is not a cause of iron deficiency anemia; pica is a symptom of iron deficiency anemia. Pica decreases the absorption of dietary iron. Other studies also showed that mean hemoglobin and plasma Fe levels were significantly lower in children with pica compared to controls.[16] Pica was present in 22.8% children. A statistically insignificant improvement in pica was observed in all three groups i.e. group A (P=0.168), group B (P=0.169) and group C (P=0.343) however Percentage improvement on pica in patients of group A, group B and group C was 66.67%, 71% and 76% respectively. The inter group comparison revealed that there was insignificant difference (P=0.802) among three groups. However therapy given in group-B had little upper edge over group-A and group-C proved best in managing pica.

A statistically highly significant (p<0.001) improvement in haemoglobin value was observed in all three groups with 9.16%,10.16% and 19.19% Percentage improvement on haemoglobin value in patients of group A, group B and group C was respectively. The inter group comparison revealed that there was statistically highly significant difference (P<0.001) among three groups. However therapy given in group-B had little upper edge over group-A and group-C proved best in managing haemoglobin concentration in blood.

Table 5: Effect of therapy (B)

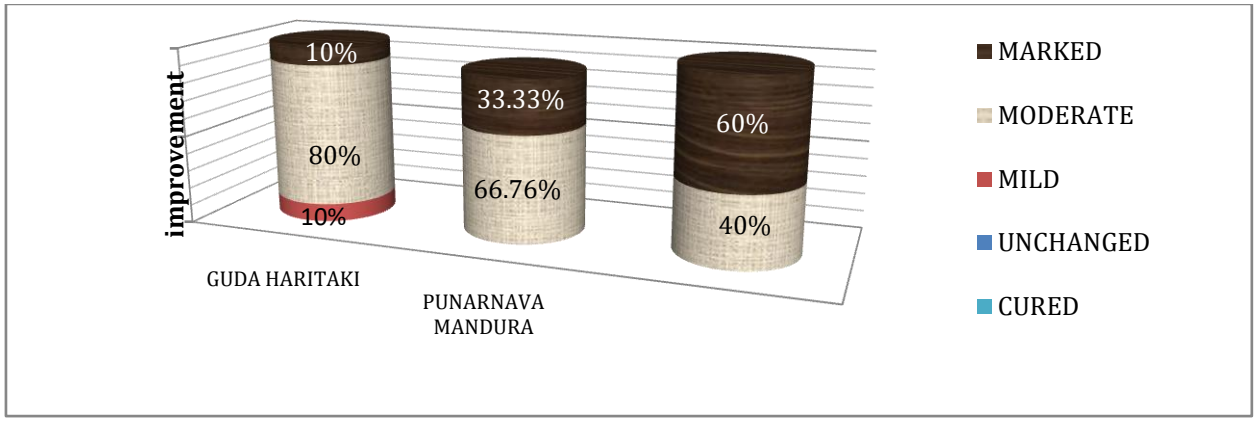
Objective parameters	Mean score			% change			SSC	MSC	F value	P value	Result
	Df_a	Df_b	Df_c	Df_a	Df_b	Df_c					
	n = 10	n = 9	n = 10	n = 10	n = 9	n = 10					
HB	0.930	1.033	1.864	9.16	10.16	19.19	11.304	0.404	13.838	<0.001	HS
Sr.Ferritin	0.798	0.243	1.392	4.20	0.69	6.80	102.133	3.648	1.114	0.351	IS
MCV	2.825	3.272	4.023	3.76	4.43	5.47	386.93	13.89	2.510	0.111	IS
MCH	0.400	1.156	0.180	01.51	4.37	0.65	88.130	3.148	0.649	0.535	IS
MCHC	0.337	1.75	0.860	0.96	5.03	2.45	62.94	2.248	2.570	0.106	IS

A statistically insignificant change in Sr. Ferritin was observed in all three groups i.e. group B (P=0.127), group A (P=0.804) and group C (P=0.003). Percentage improvement on Sr. Ferritin in patients of group A, group B and group C was 0.69%, 4.2% and 6.80% respectively. The inter group comparison revealed that there was insignificant difference (P=0.351) among three groups. A statistically significant improvement in MCV, MCH and MCHC was observed in all three groups. The inter group comparison revealed that there was insignificant difference among three groups. Rests of investigations (TLC, DLC, ESR etc.) were under normal range before and after the therapy.

Table 6: Overall effect of therapy

Groups	Cured	Marked improvement	Moderately improvement	Mildly improvement	Unchanged	Total
Gr. A	00	01(10%)	08(80%)	01(10%)	00	10
Gr. B	00	03(33.33%)	6(66.67)	00	00	09
Gr. C	00	06(60%)	4(40%)	00	00	10
Total	00	10(34.48%)	18(62.06%)	01(3.44%)	00	29

Figure 3: Overall effect of therapy



After treatment, the trial Group A, one patient (10%) showed marked improvement, 8 patients (80%) showed moderate improvement and 01 patient (10%) showed mild improvement and none of the patient remains unchanged. In group B, three patients (33.33%) showed marked improvement and 6 patients (66.67%) showed moderate improvement whereas none of the patient remains unchanged. In group C, 6 patients (60%) showed marked improvement and 4 patients (40%) showed moderate improvement and none of the patient remains unchanged. The study shows that *combination Punarnava mandura* and *Guda haritaki* can be considered to be most effective whereas *Punarnava mandura* is more effective than *Guda haritaki* for the correction of microcytic and hypochromic anemia. All the patients were examined biweekly for evaluation of any adverse drug reaction. The drugs were tolerated well and not a single patient exhibited any adverse symptom.

Ingredients of *Guda haritaki* have *Madhura* and *Kashaya rasa* and predominance of *Laghu Guna*. *Madhura* and *Kashaya rasas* perform *Pitta shamaka* function which breaks the pathogenesis of *Pandu roga* prior to *Hridaprapti* of vitiated *Pitta dosha.* The ingredients like *Haritaki* and *Madhu help in Kostha shodhana* which leads to the expulsion of vitiated *Pitta* from GI tract. *Vipaka* of most of the ingredients of the formulations is *Madhura, which* help in formation of optimum quantity of *Dhatus,* nourishes *Manna* and *Indriyas* and also alleviate vitiated *Vata Dosha*. *Madhura Vipaka* also increases the vital strength. *Guda haritaki* contains *Deepana, Pachana* dravya which regularize gastric Ph through its *Ushna Veerya* which also helps in clearing *Srotorodha.* Improvement in digestion and metabolism leads to proper *Dhatu Poshana*. *Guda* is a natural source of iron. It has got *Raktakrita* property. The iron fraction of *Guda* along with *Madhu* provides optimum amount of iron which is required for normal erythropoiesis. *Madhu* is a source of vitamin C which helps in absorption of iron.

Analysis of pharmacodynamic properties of *Punarnava Mandura* reveals that maximum ingredients of the formulation have *Katu* and *Tikta* Rasa and predominance of *Laghu Guna*. *Tikta* and *Katu Rasas* perform *Agnideepana* function which increase the metabolism and reduces the formation of *Ama. Vipaka* of most of the ingredients of the formulations is *Katu* and *Madhura*. *Madhura vipaka* help in formation of optimum quantity of *Dhatus,* nourishes *Manna* and *Indriyas* and also alleviate vitiated *Vata Dosha*. *Madhura vipaka* also increases the vital strength. *Katu vipaka* helps in regularization of metabolism. The ingredients like *Danti* and *Trivrita* help in *Kostha shodhana* which leads to vitiated *Pitta nishkasana* from GI tract. This activity is very essential in breaking the pathogenesis of *Pandu*. The *Krimihara* property of different ingredient of the formulation like *Vibhitaki, Haridra, Vidanga, Maricha, Musta* etc may be beneficial in cases of *Mritika bhakshana janya Pandu* and worm infestation. *Punarnava Mandura* contains *Deepana, Pachana dravyas*, which regularize gastric Ph through their *Ushna* and *Tikshna Guna* and *Ushna Veerya* helps in clearing *Srotorodha.* So improvement in metabolism and digestion leads to proper *Dhatu Poshana*. *Mandura Bhasma* is a natural source of iron. It has got *Raktavriddhikara* property. The iron fraction of *Mandura* provides optimum amount of iron which is required for normal erythropoiesis. *Amalaki* is richest source of vitamin C which helps in absorption of iron. *Triphala* is *Rasayana*, *Trikatu* is *Deepana*, and *Trimada* has *Pachana* properties. Activity of *Punarnava Mandura* gets potentiated due to presence of *Gomutra,* which has therapeutic attribute like- *Panduhara, Mutrala, Shophhara, Krimihara* and *Deepana. Punarnava mandura* is thus capable of executing *Samprapti Vighatana* of *Pandu* at various levels. Apart from this it also possess *Rasayana* property and has got *Vyadhi pratyenika* effect on *Pandu.*

CONCLUSIONS

Prevalence of Anaemia among school going children in Distt. Kangra was observed to the tune of 69%.[18] Important determinates of anaemia observed in survey study were adolescent age, female gender, excessive menstruation, lower socio-economic status, low birth weight , caesarean section delivery, vegetarian diet, not having history of exclusive breast feeding and dewormification. In adolescent age group iron deficiency Anaemia is comparatively more common among females. Therapy given in group-C where patients were managed with *Guda Haritaki* as well as *Punarnava Mandura* proved best in management of *Pandu* in comparison to group A and B where patients were managed with *Guda Haritaki* and *Punarnava Mandura* respectively. No untowards effects were observed in all the three groups during the entire trial period.

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