

# Efficacy of *Pandughni Vati* & *Punarnavadi Mandura Vati* in the management of *Pandu* w.s.r. iron deficiency anemia in children- An open labelled comparative clinical trial

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## Abstract

**Background:** Anemia is a public health problem worldwide, and its prevalence in India is higher than any other south Asian countries. Iron deficiency anemia (IDA) is having larger share out of all types of anaemia's. Symptomatology of IDA resembles with *Kapha* dominant variety of *Pandu*. *Pandughni Vati* (PV) and *Punarnavadi Mandura Vati* mentioned in Ayurveda are being used in clinical practice since long. **Aim:** To assess the efficacy of *Pandughni Vati* and compare its clinical efficacy with *Punarnavadi Mandura Vati* in the management of *Pandu* w.s.r. iron deficiency anemia in children. **Materials and methods:** Present clinical study was a randomized trial for management of iron deficiency anemia aged 2–16 years. Out of total 91 patients enrolled, 60 completed the study and divided into two groups. In group A, *Pandughni Vati* (trial drug) and in group B, *Punarnavadi Mandura Vati* in the management of *Pandu* w.s.r. iron deficiency anemia in children. (standard drug) were given to 30-30 patients respectively for a duration of 90 days in age specific doses. Patients were assessed by clinical signs and symptoms of *Pandu* and investigation parameters like complete blood count, serum iron, serum ferritin and total iron binding capacity (TIBC) on baseline and after 90 days of treatment. Statistical analysis was carried out by Sigma Stat software. **Results:** On comparison, highly significant difference was found between two groups in subjective parameters such as *Panduta* (pallor), *Daurbalya* (weakness), *Hridhrava* (palpitation), *Akshikuta Shotha* (periorbital oedema), *Pindikodweshntana* (leg cramps) and *Shwasa* (breathlessness) whereas objective and saturation percentage except serum ferritin. **Conclusion:** The study revealed that, both the drugs; *Pandughni Vati* and *Punarnavadi Mandura Vati* were equally effective in the management of IDA so, it could be concluded that *Pandughni Vati*, can be used as mineral-free, safe, easily obtainable, palatable, cost-effective alternative drug of choice in alternative of *Punarnavadi Mandura* in iron deficiency anemia in children.

**Keywords:** Anemia, *Pandu*, *Pandughni Vati*, *Punarnavadi Mandura*

## Introduction

Anemia is a public health problem worldwide.<sup>[1]</sup> Prevalence of anemia in India is higher than any other south Asian countries.<sup>[2]</sup> In national family health survey-5, the prevalence of anemia in 6–59 months of age group children is 67.1% in India<sup>[3]</sup> and in Gujarat it is 80% as well as this ratio is 59% in the adolescent girls age group.<sup>[4]</sup> Out of all types of anemia, iron deficiency anemia (IDA) is the most common in children, it impairs physical growth, cognitive development, immunity; affects school performance and causes fatigue and reduced work capacity.<sup>[5]</sup>

*Pandu* can be referred to anemia based on aetiology, symptomatology and treatment of it mentioned in *Ayurveda* classics. In *Ayurveda*, *Loharaja* (iron dust) has been

recommended as the best medicine for the treatment of *Pandu*,<sup>[6]</sup> which shows that the ancient scholars were well aware of the role of iron deficiency in the pathogenesis of the disease and hence considering this, *Punarnavadi Mandura* (PM),<sup>[7]</sup> which is widely used and evaluated<sup>[8]</sup> for its role in *Pandu* was selected as standard control in this study. Its contents are *Punarnava* (*Boerhaavia diffusa* Linn), *Trivrita* (*Operculina turpethum* Linn.), *Shunthi* (*Zingiber officinale* Rosc.),

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*Pippali* (*Piper longum* Linn.), *Maricha* (*Piper nigrum* Linn.), *Vidanga* (*Embelia ribes* Burm. f.), *Devadaru* (*Cedrus deodara* (roxb.) Loud.), *Chitraka* (*Plumbago zeylanica* Linn.), *Kushtha* (*Saussurea lappa* C. B. Clarke), *Haridra* (*Curcuma longa* Linn.), *Daruharidra* (*Berberis aristata* DC), *Amalaki* (*Emblia officinalis* Gaertn.), *Haritaki* (*Terminalia chebula* Retz.), *Bibhitaki* (*Terminalia belerica* Roxb.), *Danti* (*Balio spurmummontanum* Muell.-Arg.), *Chavya* (*Piper retrofractum* Vahl.), *Indrayava* (*Holarrena antidysentrica* Wall.), *Pippali* (*Piper longum* Linn.), *Pippalimula* (*Piper longum* Linn.), *Musta* (*Cyperus rotundus* Linn.) each one part, *Mandura Bhasma* (incinerated red oxide of iron) 40 part and cow's urine 160 parts.

But administration of metallic preparations requires special cautions in children.<sup>[9]</sup> Hence, *Pandughni Vati* (PV), which is a non-metallic herbal combination being used since many years at Institute of Teaching and Research in Ayurveda (ITRA), Kaumarbhritya OPD was intended to evaluate and compare with metallic preparation *Punarnavadi Mandura*. *Pandughni Vati* contains *Amalaki* (*Emblia officinalis* Gaertn.), *Bibhitaki* (*Terminalia belerica* Roxb.), *Punarnava* (*Boerhaavia diffusa* Linn), *Vidanga* (*Embelia ribes* Burm.f.), *Shunthi* (*Zingiber officinale* Rosc.), *Pippali* (*Piper longum* Linn.), *Maricha* (*Piper nigrum* Linn.), *Katuki* (*Picrorhiza kurroa* Royle ex Benth.) one part each. These powder was triturated for 6 times one by one; once with juice of *Kumari* (*Aloe barbadensi* s Mill) and cow's urine each; twice with *Punarnava* (*Boerhaavia diffusa* Linn.) and *Amalaki* (*Emblia officinalis* Gaertn.) decoction each.

### Aim and objective

1. To evaluate and compare the efficacy of the *Pandughni Vati* with *Punarnavadi Mandura Vati* in the management of *Pandu* w.s.r. to iron deficiency anemia in children.

### Material and methods

The study got approved by Institutional Ethics Committee (no.: PGT/7-A/Ethics/2008-09/2520, dated: November 24, 2008) and trial was registered in Clinical Trial Registry of India (Reg. No. 2011/12/002310 dated: December 30, 2011). Patients visiting the outpatient department of Kaumarbhritya Department of Institute of Teaching and Research in Ayurveda, Jamnagar were thoroughly examined for clinical signs and symptoms of *Pandu* along with the necessary haematological and biochemical investigations.

Subjects were enrolled for the study considering the criteria of inclusion, after getting the consent. The registered patients were allocated into two groups, using the randomization.

*Pandughni Vati* was given in the dose of 3, 6.5 and 10.5 g per day in trial group A and *Punarnavadi Mandura* was given 1.5, 3 and 5 g per day in standard group B for the age group of 2–6, 7–11 and 12–16 years respectively and was given in three divided doses after meal with warm water for a period of 90 days. No any concomitant medicine was given during

this period. After completion of the clinical trial, the patients were followed up for further 2 months.

### Diagnostic criteria

Patient was diagnosed on the basis of Ayurvedic classical signs and symptoms of *Pandu* and level of haematological parameters or haematocrit<sup>[10]</sup> (Hb%11.5, MCV 80fl, MCH 30pg, MCHC 32-36g/dl) below the range of values occurring in healthy children. Patients were also examined on the basis of specially prepared proforma.

### Inclusion criteria

Patients between the age of 2 and 16 years, irrespective of gender having Hb% below 11.5 g/dl, having transferrin saturation index below 16 and peripheral blood picture showing microcytic-hypochromic Red blood cells (RBCs) were included for the study.

### Exclusion criteria

Patients age <2 years and >16 years, having Hb% below 6.5% g/dl having other types of anemia, hemoglobinopathies especially Thalassemia, any associated cardiac complaints, conditions causing chronic blood loss like piles, anal polyps, haemophilia, etc., regular/irregular menstrual cycle with heavy blood loss in adolescent girls, any systemic illness like malignancy, juvenile diabetes mellitus, severe renal, hepatic, cardiac diseases, collagen vascular diseases etc., and chronic infectious diseases like tuberculosis, typhoid, malaria etc., were excluded from the study.

### Criteria for assessment

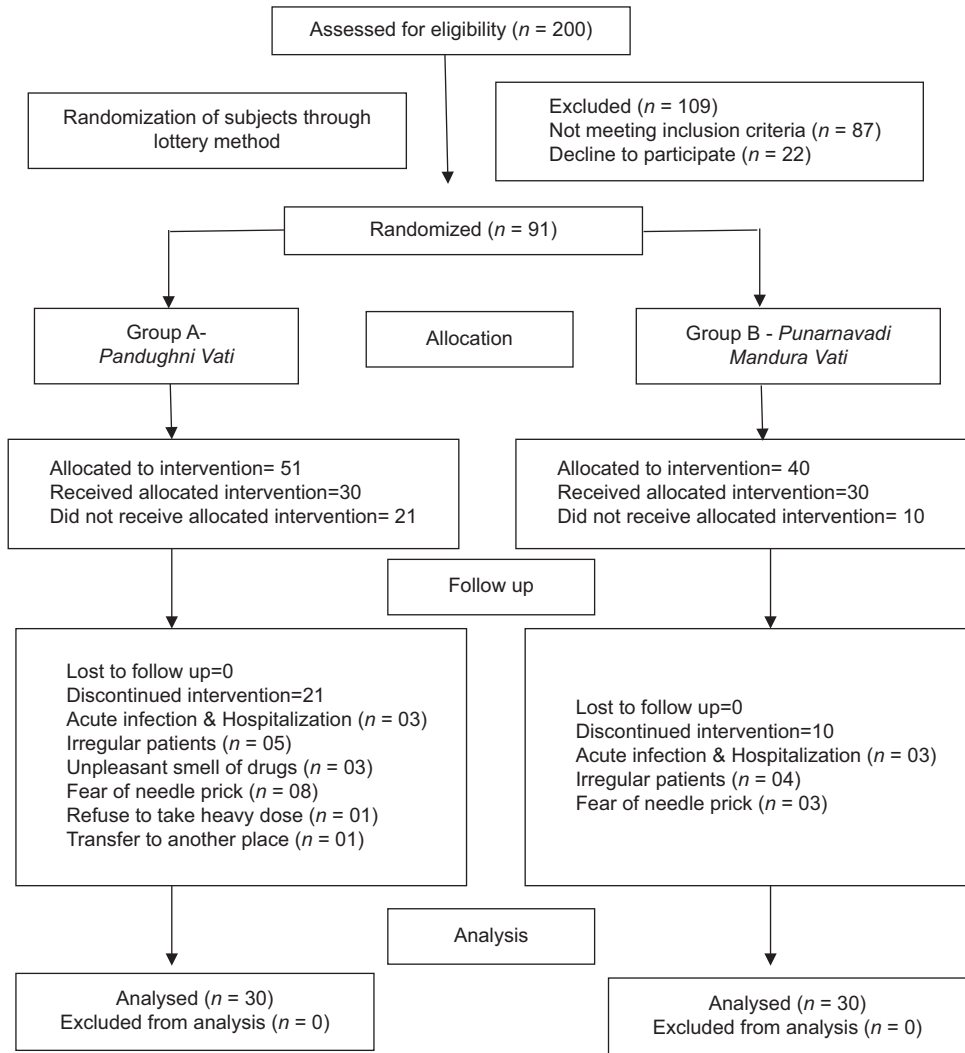
Assessment was done by considering changes in the subjective as well as objective parameters before the treatment and after the treatment. Subjective parameters include sign and symptoms of *Pandu* such as *Panduta* (pallor), *Daurbalya* (weakness), *Hridrava* (palpitations), *Akshikuta Shotha* (periorbital oedema), *Pindikodweshtana* (leg cramps) and *Shwasa* (breathlessness) whereas objective parameters includes haemoglobin percentage, serum ferritin, serum iron and serum total iron binding capacity.

### Statistical analysis

Mann–Whitney *U*-test was used to compare the effect of therapies between the two groups for nonparametric data. Student's unpaired *t*-test was applied for the parametric data to compare the effect of therapies of two groups. Wilcoxon Signed Rank Test was used to evaluate the effect of therapy for nonparametric data and paired *t*-test for parametric data of within the group. Tests were performed using Sigma Stat 3.1 software 2005 by Jandel scientific software, San Jose, California.<sup>[11]</sup> The value were considered significant at the levels of  $P < 0.05$ .

### Observations

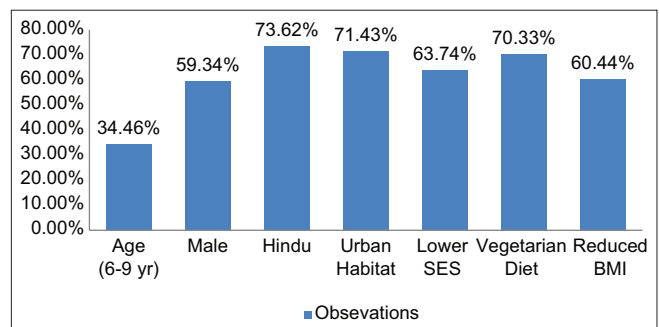
The registered patients (out of total 91, 60 completed the treatment) were allocated into two groups; in group *Pandughni Vati* out of 51 registered 30 completed, while in group *Punarnavadi Mandura* out of 40 registered, 30 completed the research protocol [Chart 1].



**Chart 1:** Consort Flow Chart

In group A (*Pandughni Vati*), out of 21 discontinued patients, 03 had acute infection and get hospitalized, 05 had poor drug compliance, 03 stopped medicine by complaining unpleasant smell of drugs, 08 had fear of needle prick for after treatment (AT) investigation, 01 patient refused directly to take medicine and 01 patient transferred to another place.

In group B (*Punarnavadi Mandura*), out of 10 discontinued patients 03 had acute infection and get hospitalized, 04 had poor drug compliance and 03 had fear of needle prick for AT investigation. Maximum numbers of patients were in the age group of 6–9 years (38.46%), male (59.34%), Hindu (73.62%), from urban habitat (71.43%), maternal education secondary (34.07%), father education secondary (41.76%), lower class (63.74%), vegetarian (70.33%), reduced body mass index (60.44%). Cardinal features of *Pandu* like *Panduta* (100%), *Daurbalya* (96.7%), *Shwasa* (47.25%), *Hridhrava* (21.98%), *Akshikutashotha* (14.29%) and *Pindikodweshstana* (39.56%) were observed in the registered patients of this clinical trial. Chronicity (0–6 months) was observed in 37.36% of the patients [Chart 2].



**Chart 2:** 2-Observations, SES: Socioeconomic status, BMI: Body mass index

## Results

On chief complaints *Pandughni Vati* and *Punarnavadi Mandura* group provided highly significant results on *Panduta*, *Daurbalya* and *Shwasa* while group B *Punarnavadi mandura* shows highly significant results on these symptoms along with *Pindikodweshstana*. [Table 1] On haematological

parameters both groups provide similar insignificant changes except on mean corpuscular haemoglobin (MCH) and MCH concentration on which group B (*Punarnavadi mandura*) provided significant improvement. Hb% was increased significantly in both the groups. [Table 2] group A *Pandughni Vati* provided significant increase on serum Ferritin whereas group B *Punarnavadi mandura* group

provided significant increase on serum Iron and Transferrin saturation. TIBC shown insignificant difference in both the groups. [Table 3]

On comparison, highly significant difference was found between two groups in *Panduta*, *Daurbalya*, *Shwasa* and *Pindikodweshтана*. [Table 4] Statistically insignificant difference was found on Hb%, packed cell volume (PCV),

**Table 1: Effect of *Pandughni Vati* and *Punarnavadi Mandura Vati* on chief complaints**

Features	Group	n	BT	AT	Percentage of relief	SD	SE	w	P
<i>Panduta</i> (pallor)	A (PV)	30	4.53	0.73	83.82	1.10	0.20	465	<0.001
	B (PM)	30	4.80	1.13	76.39	0.92	0.17	435	<0.001
<i>Daurbalya</i> (weakness)	A (PV)	29	1.86	0.34	81.48	0.63	0.12	406	<0.001
	B (PM)	29	2.07	0.34	83.33	0.59	0.11	406	<0.001
<i>Shwasa</i> (breathlessness)	A (PV)	13	3.15	0.15	95.12	1.41	0.39	91	<0.001
	B (PM)	16	3.13	0.25	92.00	1.26	0.31	120	<0.001
<i>Hridhrava</i> (palpitations)	A (PV)	10	1.80	0.30	83.33	0.71	0.22	55	0.002
	B (PM)	5	1.60	0.20	87.50	0.89	0.40	10	0.125
<i>Akshikuta Shotha</i> (periorbital edema)	A (PV)	4	2.00	0.25	87.50	0.96	0.48	10	0.125
	B (PM)	5	1.20	0.00	100	0.84	0.37	10	0.125
<i>Pindikodweshтана</i> (leg cramps)	A (PV)	7	1.57	0.14	90.91	0.53	0.20	28	0.016
	B (PM)	16	1.94	0.13	93.55	0.66	0.16	120	<0.001

W: Wilcoxon signed rank test coefficient, PV: *Pandughani Vati*, PM : *Punarnavadi Mandura Vati*, BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error

**Table 2: Effect of *Pandughni Vati* and *Punarnavadi Mandura Vati* on hematological parameters**

Parameters	Group	n	BT	AT	Percentage of relief	SD	SE	t	P
Hb (g/dL)	A (PV)	30	10.16	10.54	3.75	0.69	0.13	3.02	<0.01
	B (PM)	30	10.41	10.89	4.58	0.48	0.11	4.53	<0.001
PCV (%)	A (PV)	30	32.22	32.84	1.9	1.95	0.36	1.72	>0.05
	B (PM)	30	32.75	33.73	2.97	1.99	0.36	2.67	<0.05
MCV (fl)	A (PV)	30	69.85	70.53	0.97	1.62	0.29	2.31	>0.05
	B (PM)	30	73.00	74.42	1.95	3.04	0.56	2.55	<0.05
MCH (pg)	A (PV)	30	22.22	22.53	1.43	0.70	0.13	2.46	<0.05
	B (PM)	30	23.30	24.20	3.89	1.49	0.27	3.33	<0.01
MCHC (g/dL)	A (PV)	30	31.51	31.74	0.75	1.16	0.21	1.12	>0.05
	B (PM)	30	31.71	32.33	1.93	1.12	0.20	3.00	<0.01
TRBC (10 <sup>6</sup> /μL)	A (PV)	30	4.66	4.76	2.10	0.29	0.05	1.84	>0.05
	B (PM)	30	4.52	4.56	1.00	0.26	0.05	0.97	>0.05

Hb: Hemoglobin, PCV: Packed cell volume, MCV: Mean corpuscular volume, MCH: Mean corpuscular hemoglobin, MCHC: Mean corpuscular hemoglobin concentration, TRBC: Total red blood cell, PV: *Pandughani Vati*, PM: *Punarnavadi Mandura Vati*, BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error

**Table 3: Effect of *Pandughni Vati* and *Punarnavadi Mandura Vati* on biochemical markers of anemia**

Parameters	Group	n	BT	AT	Percentage of relief	SD	SE	t	P
Serum iron (IU/L)	A (PV)	30	36.41	38.02	↑4.42	7.44	1.36	1.18	>0.05
	B (PM)	30	36.33	40.12	↑10.44	8.47	1.55	2.45	<0.05
Serum ferritin (IU/L)	A (PV)	30	25.77	15.46	↓39.99	20.53	3.75	2.75	<0.05
	B (PM)	30	16.87	25.12	↑48.93	36.89	6.74	1.23	>0.05
Serum TIBC (IU/L)	A (PV)	30	382.47	389.20	↑1.76	67.09	12.25	0.55	>0.05
	B (PM)	30	399.43	395.70	↓0.93	58.44	10.67	0.35	>0.05
Transferrin saturation (%)	A (PV)	30	9.65	9.88	↑2.32	1.23	0.22	0.99	>0.05
	B (PM)	30	9.22	10.30	↑11.75	2.70	0.49	2.2	<0.05

↓Decrease, ↑Increase. TIBC: Total iron binding capacity, PV: *Pandughani Vati*, PM : *Punarnavadi Mandura Vati*, BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error



**Table 4: Comparative effect of *Pandughani Vati* and *Punarnavadi Mandura Vati* on chief complaints**

Features	n	Percentage of relief		Mean difference	U	P
		Group A (PV)	Group B (PM)			
<i>Panduta</i> (pallor)	58	83.82	76.39	0.13	900	<0.001
<i>Daurbalya</i> (weakness)	56	81.48	83.33	0.21	0.50	<0.001
<i>Shwasa</i> (breathlessness)	27	95.12	92.00	0.13	208	<0.001
<i>Hridhrava</i> (palpitations)	13	83.33	87.50	0.10	0.00	0.002
<i>Akshikuta Shotha</i> (periorbital edema)	7	87.50	100	0.55	20	0.016
<i>Pindikodweshtana</i> (leg cramps)	21	90.91	93.55	0.38	112	<0.001

U: Mann-Whitney U test coefficient, PV: *Pandughani Vati*, PM: *Punarnavadi Mandura Vati*

total red blood cell (TRBC), mean corpuscular volume (MCV) and mean corpuscular haemoglobin (MCH). [Table 5] On comparison between both the groups, serum ferritin provided significant difference. [Table 6]

## Discussion

Iron deficiency due to mal absorption is the main etiological factor in IDA, though the other factors like malnutrition, worm infestations, chronic diseases and haemorrhage also play the role in disease manifestation. Ayurveda have given pathophysiology of many diseases in which hampered *Agni* (digestive power) causes mal absorption.<sup>[12]</sup> *Pandu* is one of them, caused by *Rasa Dhatukshaya* (reduction in *Rasa Dhatu*), that leads to pallor appearance of conjunctiva, nail and face.<sup>[13]</sup>

In this study, maximum numbers of the patients were from 6–9 years of age group. Children of preschool and school going age having the highest prevalence of anemia i.e., 47.4% of their population group according to the World Health Organization, largely due to faulty nutritional choices.<sup>[14]</sup>

63.74% patients enrolled in this study belonged to lower class, which indicates sound causation of social status for this disease. This observation is in line with previous study's conclusion, patients from lower SES have higher grades of anemia than higher SES.<sup>[15]</sup>

Significant improvement was found in *Panduta*, *Daurbalya*, *Shwasa* in both the groups may be because of immunomodulation, antioxidant, hematinic and cytoprotective actions of *Amalaki*<sup>[16-18]</sup> and *Punarnava*<sup>[19-22]</sup>, which is the common ingredients of both the trial drugs. Both these drugs possess antioxidant activity and are an important source of Vitamin C, which is a potent water-soluble antioxidant to help in increasing iron absorption from the gut. *Trikatu* (*Piper longum* Linn., *Zingiber officinale* Rosc., *Piper nigrum* Linn.) is also an important content present in both the trial drugs having *Deepana* (appetizer), *Pachana* (digestive) and antioxidant properties. Its main active component is an alkaloid named as piperine which gets absorbed very quickly across the intestinal barrier, and modulate membrane dynamics thus helping in efficient permeability across the barrier. In addition *Trikatu* is bio-availability enhancer of the drug which further helps in assimilation of the drug components. Hence, it counteracts poor digestion and absorption.<sup>[23]</sup>

**Table 5: Comparative effect of group A *Pandughani Vati* and group B *Punarnavadi Mandura Vati* on hematological parameters**

Parameters	df	Percentage of relief		Mean difference	t	P
		Group A (PV)	Group B (PM)			
Hb (g/dL)	58	3.75	4.58	0.10	0.57	>0.05
PCV (%)	58	1.9	2.97	0.36	0.68	>0.05
TRBC (10 <sup>6</sup> /μL)	58	0.97	1.95	0.05	0.72	>0.05
MCV (fl)	58	1.43	3.89	0.74	1.17	>0.05
MCH (pg)	58	0.75	1.93	0.59	1.97	>0.05
MCHC (g/dL)	58	2.10	1.00	0.38	1.28	>0.05

Hb: Hemoglobin, PCV: Packed cell volume, MCV: Mean corpuscular volume, MCH: Mean corpuscular hemoglobin, MCHC: Mean corpuscular hemoglobin concentration, TRBC: Total red blood cell, PV: *Pandughani Vati*, PM: *Punarnavadi Mandura Vati*

Significant reduction in *Pindikodweshtana* was found in *Punarnavadi Mandura* group, might be because of *Mandura Bhasma*, having *Sheeta Virya* (cold potency), *Katu Vipaka* (post digestive effect with pungent taste), *Pitta-Kapha Shamaka* (pacification of *Pitta* & *Kapha*) properties and hence improves *Rasa* (plasma) and *Rakta Dhatu* (blood tissues). The ferric and ferrous fractions of *Mandura* provide sufficient amount of iron, which may helped in normal erythropoiesis leading to improvement in Hb concentration causing increase in oxygen-carrying capacity of RBCs and thus reduced ischemic-hypoxic pain in calf muscle.<sup>[24,25]</sup> Additionally *Punarnavadi Mandura* is prepared by trituration with cow urine, that may pacify *Vata Kapha*, having *Agni Vardhaka* (digestive power stimulant), *Rasayana* (rejuvenating) properties as per *Ayurveda*. The cow urine also having pharmacological properties like hematinic, cardio-protective and anti-spasmodic action.<sup>[26]</sup> *Triphala* have *Anulomana* (purgative) property and it counteract the constipation (known side effect of iron therapy) caused by iron compound of *Mandura Bhasma*.<sup>[27]</sup>

Significant increase in haemoglobin in both the groups shows that, group B *Punarnavadi Mandura* group worked by its iron content while, group A *Pandughni Vati* group might have increased the Hb due to the availability of natural iron element in *Amalaki* and *Punarnava* along with *Trikatu*, *Katuki* and *Vidanga* which improves *Agni* and helps in assimilation of dietary iron even in absence of iron supplements.

**Table 6: Comparative effect of group A *Pandughani Vati* and group B *Punarnavadi Mandura Vati* on specific markers**

Parameters	df	Percentage of relief		Mean difference	t	P
		Group A (PV)	Group B (PM)			
Serum iron (IU/L)	58	↑4.42	↑10.44	2.18	1.06	>0.05
Serum ferritin (IU/L)	58	↓39.99	↑48.93	18.56	2.40	<0.05
Serum TIBC (IU/L)	58	↑1.76	↓0.93	10.48	0.64	>0.05
Saturation (%)	58	↑2.32	↑11.75	0.86	1.59	>0.05

↓Decrease, ↑Increase. TIBC: Total iron binding capacity, PV: *Pandughani Vati*, PM: *Punarnavadi Mandura Vati*, df: degree of freedom, t: unpaired 't' test coefficient

Significant improvement was found in S. ferritin in group B *Punarnavadi Mandura* in comparison to group A *Pandughni Vati*, which may be because of Iron content in this formulation.

Significant difference between the groups were not found on any specific markers of anemia except in S. ferritin (*Punarnavadi Mandura* is more effective than *Pandughni Vati*), which indicates there was nearly equal effect of both interventions i.e., herbal *Pandughni Vati* and herbo-mineral *Punarnavadi Mandura*.

No any adverse reaction was found in patients of either of the group during the study period that indicates safety of both the drugs. Result of this study shows that, correction of digestion, metabolism and breakdown of pathogenesis with herbal medicines also provides same result as of iron containing herbo-mineral drug *Punarnavadi Mandura*.

## Conclusion

The study showed that there was no significant difference in majority of the factors analysed for management of iron deficiency anemia (IDA) in children by *Pandughni Vati* and *Punarnavadi Mandura*; except in serum ferritin (*Punarnavadi Mandura* is more effective than *Pandughni Vati*). Both interventional drugs provided improvement in parameters like pallor, weakness, breathlessness and Hb%. No any side effect was noted during this study period in either of the groups suggest its safety and hence it could be concluded that *Pandughni Vati*, can be used as mineral-free, safe, easily obtainable, palatable, cost-effective alternative drug of choice in alternative of *Punarnavadi Mandura* in iron deficiency anemia (IDA) in children.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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