Int J Ayu Pharm Chem
ISSN 2350-0204
www.ijapc.com

ORIGINAL RESEARCH ARTICLE

The Clinical Study of the Effect of *Dhatryaavleha* on *Panduroga* in Children (w.s.r. to Iron Deficiency Anaemia)

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ABSTRACT

Iron deficiency is the most common and widespread nutritional disorder in the world. According to WHO approximately 50% of all anemic patients have iron deficiency anemia. *Ayurveda* has described *Panduroga* which can be correlated with Iron DeficiencyAnemia. Because most of the symptoms and causes of *Panduroga* are as same as IDA. The present study is a Prospective Open labeled randomized control clinical trial conducted on 60 patients having *panduroga*. Patients were studied in two group's viz., Control and Trial group. Syrup Orofer was given to patients in control group & *Dhatryaavleha*given to trial group for 2 months. At the end of study we found that statistically *Dhatryaavleha* and Syrup Orofer showed equal effects in rising Hb%.

Key Words *Panduroga, Dhatyraavleha, Syrup Orofer, Anemia*

INTRODUCTION

Anaemia is present when hemoglobin level is more than two standard deviation below the mean for the child age and sex. According to third National family health survey 79% Indian children have Anaemia. Highest prevalence of Anaemia is in preschool age children.

Iron deficiency is the most common and widespread nutritional disorder in the world. As well it affects more on children and womens in developing countries. According to WHO approximately 50% of all anemic patients attributed to iron deficiency. It is more common in India because of poor socioeconomic condition, low dietary intake, malabsorption & excessive sweating. Its prevalence varies from 75% among children and 45% among adult males.

In modern medicine, there is good treatment for anaemia with considerable result but that is only for acute deficiencies anaemias. No significant therapy is there for chronic Anaemias which occur due to metabolic defects. Ayueveda can provide better management of this area. In Ayrveda*Rakta* (Blood) has been considered as the key factor for the Jeevana, Prinana, Dharana and Poshana karma of the Body. Blood consists of various cells,

including red blood cells which contain hemoglobin, white blood cells which are the basis of the body's defense mechanism and immunological functions of the body and platelets which are required for plugging any breach or leak in the circulating vessels.

Panduroga is a disease of *Rasavahastrotasa.Charakacharya*and many other samhita has described *Panduroga* in detail. *Charakacharya* and other*samhita's* have described the *Nidan*(causes), *Lakshana* (symptoms) and*Chikitsa* (treatment) of *Panduroga*in detail. Symptomatology of IDA can be correlated to *Panduroga* because most of symptoms and causes of the *Panduroga* are same as IDA.

AIMS AND OBJECTIVES

AIMS

The clinical study of effect of *Dhatryaavlehaon Panduroga* in children (w.s.r. to Iron deficiency Anaemia).

OBJECTIVES

1. To study effect of *Dhatryaavleha* on *Panduroga.*
2. To study the benefits of ancient medicine in modern era.

MATERIALS AND METHODS

Materials

1) Children suffering from *Panduroga*(IDA).
2) *Dhatryaavleha*
3) Elemental Iron preparations

Patients:

Patients were selected from OPD hospital.

Diagnostic criteria:

1. *Ayurvedic:*

a. Panduta
b. Akshikutshotha
c. Shramashwasa
d. Agnimandya
e. Dourbalya

2. Modern:

a. Hb% < 11 gm/dl

Criteria for Inclusion:

Age - 4 – 12 years

Sex - Male and Female

Hb% - Patients having Hb% of 8 to 11 gm%.

Patients of Iron deficiency Anaemia only.

Patients having symptoms of *Panduroga*.

Criteria for exclusion :-

1) Children less than 4 yrs and more than 12 yrs of age.
2) Other types of Anaemia.
3) Patients having Hb% of less than 8 gm%
4) Other severe systemic illness

Withdrawal Criteria:

- If patient develop some serious complication during the course of trial.

Criteria's for relief:

Objective –Increased Hb%.

Subjective – Improvement in subjective criterias.

3.*DHATRYAAVLEHA*:

Method of Preparation of Drug:

Dhatryaavleha was prepared accordingly to classical method of *Dhatrya-Avaleha* preparation as given in Ch .Chi. 16 / 100- 102 *Pandurogadhikara.*

Galley Proof

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ORIGINAL RESEARCH ARTICLE

द्विपलांशा तुगाक्षिरीनागरं मधुयष्टिका ।
प्रास्थिकीपिप्पलीद्राक्षांशर्कराधतुलाशुभम् ॥
धात्रीफलरसद्रोणेचुर्णितंलेहवत्पचेत् ।
शीतंमधुप्रस्थयुतं लिह्यात पाणीतालतत: ।
हन्त्येषकामलापित्तपाण्डुकासहलीमकम् ॥
– च. चि. १६/१००–१०२

Table 1 Ingredients

S. N.	Drug name	Family	Latin name	Part used	Propoti-on
1	*AmalakiRasa*	Euphorbiacea-e	Embellica officinalis	Fresh fruits	1 Dron
2	*Yastimadhu*	Leguminoceae	Glycyrrhiza glabra	Root	2 Pal
3	*Pippali*Dried	Piperaceae	Piper longum	fruit	1 Prasth
4	*Shunthi*	Zingiberaceae	Gingiber officinale	Dried rhizome	2 pal
5	*Draksha*	Vitaceae	Vitisvinifera	Ripe fruit	1 Prasth
6	*Vansha lochana*	Graminae	Bambusaarundinacea	Extract	2 pal
7	*Sharkara*	Graminae	Saccharumofficinarum	Crystals	½ Tula
8	*Madhu*	-	Honey	Nectar	Prakshepdravya

Standardization of Drugs:

Standardization of the drugs under trial was done in central Govt. certified Laboratory.

Table 2 The physio-chemical values of *Dhatryaavleha* are as follows-

SR.NO.	Parameter	Result
1	Water soluble extractive	56%
2	Alcohol soluble extractive	52%
3	Total Ash	1.5%
4	Acid insoluble ash	0.3%
5	pH	6.7

3. Elemental iron Preparation (Sy.Orofer)

- It contains following nutrients-

Iron hydroxide polymaltose complex equivalent to elemental iron - 50 mg/ 5 ml.

- Syrup Orofer was purchased directly from private medical stores by the patients.

METHODOLOGY

It is prospective Open labeled randomized control clinical trial. Thorough history and the complaints of the patients were taken in their chronological order.

Each and every patient was carefully examined clinically for general and systemic examination. Full explanation about the trial was given to the parents of each patient and informed written consent of parents of each and every patient was taken before the commencement of treatment, after that total 60 patients were selected for present clinical trial on the basis of clinical diagnosis. Total 60 patients of *IDA* were randomly selected and equally divided into two groups.

For treatment purpose children of both sexes (M/F) are selected and all patients are grossly divided in to two groups as follows-

1. Trial group.
2. Control group.

STUDY DESIGN:

It is prospective Open labeled randomized control clinical trial.

1. TRIAL GROUP:

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Period of trial – 60 days

Selection of patient – Children of age group 4 – 12yr suffering from iron deficiency Anaemia.

Sample size - 30

Medicine- *Dhatryaavleha*

Dose - Calculated by the Reference of *SharangdharSamhita.*

i.e. 4 yr – 4 Masa, 5 yr - 5 masa, 12yr – 12 masa (1 masa = 1.5 gm)

Drug administration - orally after meals twice a day.

बालस्यप्रथमेमासिदेयाभेषजरत्तिका।

अवलेहीकृतैकैव क्षीरक्षौद्रसिंताघृतैः ॥

वर्धयेतावदेकैकांयावद्भवतिवत्सराः ।

माषैः वृद्धिः तद्उर्ध्वस्यात्यावत्षोडशवत्सराः।

ततः स्थिराभवेद्यावदवर्षाणिसप्ततिः ॥

शा.सं.पुर्वखंड ८

2.CONTROL GROUP:

Elemental Iron [Iron (III) hydroxide polymaltose complex] supplementation given as per dose i.e. 5 mg / kg / day in two divided dose for 60 days.

CRITERIA OF ASSESSMENT

Observation will be noted down evaluating the following criteria.

A) Subjective Parameters:

***Panduta* (Pallor) with gradation :**

Panduta all over body - +++

NakhanetraPanduta - ++

Panduta only at *Netra*- +

Absent - 0

1. *Akshikutashotha* (Puffiness of the face) with gradation:

Swelling all over face - +++

Swelling on cheeks - ++

Swelling all around eye - +

Absent - 0

2. *Shramashwas* (Exertional breathlessness) with gradation :

*Shramashwas*while walking - +++

During average activity - ++

During play/running - +

Absent -0

3. *Agnimandya*(Anorexia) with gradation :

No feeling to eat in whole day (24 hr) - +++

Take diet forcefully (once day) - ++

Taking diet 2 times in a day - +

Taking regular diet - 0

4. *Daurbalya* (feeling of weakness) with gradation :

While walking - +++

During average activity - ++

During play/running - +

Absent-0

B) Objective Parameters:

Hb% taken on 0^{th}, 30^{th} and 60^{th} day.

Duration of work: 60 days

Follow up:

0^{th}, 30^{th}, 60^{th} day.

Investigations:

CBC with Morphology of RBC done on 0^{th}, 30^{th}, 60^{th} day.

Age wise dividation of the patients:

Divided in two groups-

1. 4-8 years

2. 8-12 years.

Place of Work:

OPD and IPD patients of our institute if required help of other institution also be taken.

Treatment Procedure:

Before starting treatment all the patients deworming medicine. Then trial group patients were treated with *Dhatryaavleha* given as per avlehamatra in *Sharangdharsamhita* in two dived dose after meal for 60 days.

The control group patients were treated with Elemental Iron [Iron (III) hydroxide polymaltose complex] oral supplementation (Syrp.Orofer) given as per dose i.e. 5 mg / kg / day before meal for 60 days.

Statistical Analysis:

Both groups will be applied 'f' ratio test for the quantitative data and x^2 test for qualitative data to test homogeneity.

Quantitative data - Paired 't' testapplied in each group to assess efficacy of treatment. Unpaired 't' test applied to compare results among both groups.

Qualitative data – Wilcoxan signed rank testapplied in each group to assess efficacy of treatment. Mannwhitney testapplied to compare results among both groups.

OBSERVATION

Following observations were made and results obtained.

Age wise distribution of the patients is explained in Table no. 3 and Fig. no. 1

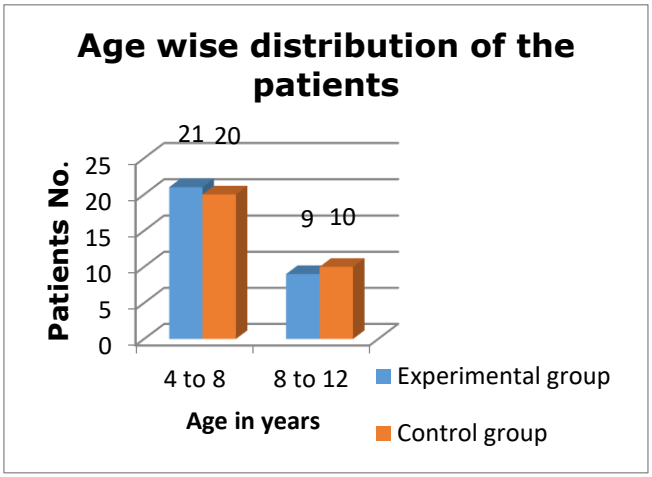

Figure 1 Age wise distribution of the patients

Table 3 Age wise distribution of the patients

Sr. No.	Age groups in years	Experimental group	Control group	Total	Percentage
1.	4-8	21	20	41	68%
2.	8-12	09	10	19	32%
Total		30	30	60	100%

The above table shows that in both groups patients of Anaemia more in 4-8 years age group i.e 68% by statistical analysis $x^2 = 0.077$, $P > 0.05$ (x^2 table = 3.84) which is insignificant so both groups are homogenous. Sex wise distribution of the patients is given in Table 4 and Figure No.-2.

Table 4 Sex wise distribution of the patients

Sr. No.	Sex	Experimental group	Control group	Total	Percentage
1.	Male	18	11	27	45%
2.	Female	12	19	33	55%
Total		**30**	**30**	**60**	**100%**

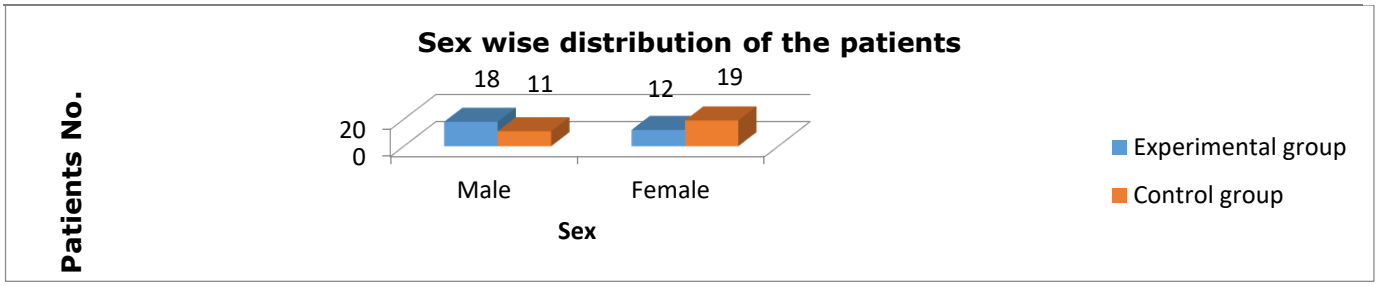

Figure 2 Sex wise distribution of the patients

The above table shows that in both groups female patients are more affected i.e.55% by statistical analysis $x^2 = 3.27$, $P > 0.05$ (x^2 table = 3.84) so both groups are homogenous.

Patients were examined carefully and thoroughly and findings were recorded before, during and completion of treatment.The most commonly seen clinical features of *Panduroga* were taken as parameters for analysis. These are *Panduta*(Pallor), *Agnimandya*(anorexia), *Daurbalya* (generalised weakness), *Shramashwas* (dyspnea), *Akshikutashotha* (Puffy face) along with haemoglobin concentration. Hb% percentage was noted in the form of quantitative data.

Remaining parameters were recorded in the form of qualitative data which was converted to quantitative form for the convenience of statistical analysis.

In both the groups paired 't' ratio test was applied for the quantitative data and x^2 test for qualitative data to test homogenecity.

The level of significance was set 5% $p < 0.05$, t calculated > t table indicates significance of findings.

RESULTS

A)Haemoglobin percentage :-

Effect of Treatment on Hb% in Trial Group is explained in table no. 5.

Table 5 Effect of Treatment on Hb% in Trial Group

Sr.No.	Follow up	BT	30 day	AT
1.	Mean	8.81	9.57	10.81
2.	S.D.	0.3922	0.6409	1.007

Change in Hb% in trial group is explained in Table no. 6.

Table 6 Change in Hb% in trial group

Change in Hb%	0-30	30 – 60	BT –AT
Mean difference	0.75	1.2	2.0
SD	0.5310	0.8534	0.7643
SE	0.1370	0.2202	0.1972
T calculated	5.474	5.44	10.14
P	<0.05	<0.05	<0.05
t table	2.05	2.05	2.05

As per table-6, in the trial group, by applying paired 't' test at P<0.05 for a 0-60 day follow-up; 't' calculated was found to be 10.14 which is greater than 't' table i.e. 2.05. Therefore, treatment is significantly effective in rising the Hb%. Also, for 0-30 day and 30-60 day follow up 't' calculated > 't' table.When we compare 't' calculated of 0-30 day and 30-60 day follow up, 't' calculated of 0-30 day is slightly greater than 't' calculated of 30-60 day which means in first 30 days there is slightly more rise in Hb% than next 30 days.

Effect of Treatment on Hb% in control Group is explained in table no.7.

Table 7 Effect of Treatment on Hb% in control Group

Sr.No.	Follow up	BT	30 day	AT
1.	Mean	8.67	9.52	10.92
2.	S.D.	0.4968	0.5003	0.5320

Change in Hb% in control group is given in Table no. 8.

Table 8 Change in Hb% in control group

Change in Hb%	0-30	30 – 60	BT –AT
Mean difference	0.85	1.39	2.247
SD	0.4988	0.5166	0.5147
SE	0.1287	0.1333	0.1328
T calculated	6.63	10.45	17.28
P	<0.05	<0.05	<0.05
t table	2.05	2.05	2.05

As the above table shows that in control group by applying paired 't' test at P<0.05 for 0-60 day follow up 't' calculated is 17.28 which is greater than 't' table i.e. 2.05 so treatment is significantly effective in rising the Hb%. Also for 0-30 day and 30-60 day follow up 't' calculated > 't' table.

When we compared 't' calculated of 0-30 day and 30-60 day follow up 't' calculated of 0-30 day is greater than 't' calculated of 30-60 day which means in last 30 days there is more rise in Hb% than first 30 days.

As the above table shows that in control group by applying paired 't' test at P<0.05 for 0-60 day follow up 't' calculated is 17.28 which is greater than 't' table i.e. 2.05 so treatment is significantly effective in rising the Hb%. Also for 0-30 day and 30-60 day follow up 't' calculated > 't' table.

When we compared 't' calculated of 0-30 day and 30-60 day follow up 't' calculated of 0-30 day is greater than 't' calculated of 30-60 day which means in last 30 days there is more rise in Hb% than first 30 days.

Mean Hb% of Control And Trial Group is given in table no. 9 and Figure 3.

Table 9 Mean Hb% of Control and Trial Group

GROUP	BT	AT
TRIAL	8.81	10.81
CONTROL	8.67	10.92

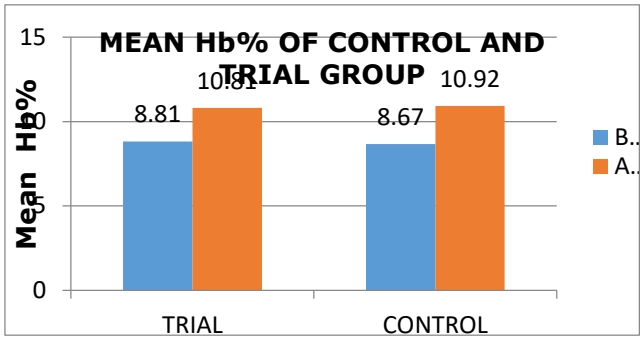

Figure 3 Mean Hb% Of Control And Trial Group

When F ratio test is applied to BT Hb% of control and trial group then – Calculated 'F' value is= 1.537, df=29 . 'F' Table =4.20 at P>0.05 .

So, F calculated < F table. So test is stasticaly insignificant i.e. It means observation in both groups is same at baseline i.e. there is no difference in Hb% of patients in both groups i.e Both groups are homogenous. Comparative effect of treatment on Hb% in trial group and control group (Unpaired 't' test applied) for 0 -60 day follow up given in Table no. 10.

Table 10 Comparative effect of treatment on Hb% in trial group and control group

Groups	Mean Difference	Combine S.D.	S.E.	T cal	P	t table
T-C	0.247	0.6519	0.1682	1.46	>0.05	2.05

When Both the groups were compared for rise in Hb%, it was found that there is total difference of 0.247gm% in Hb with calculated 't'value 1.46 and table value of 't' is 2.05 which means t calculated< t table. So calculated 't' value is insignificant at P<0.05. Hence both group shows equal rise in Hb% for 0 - 60 day follow up.

Comparative effect of treatment on Hb% in trial group and control group(Unpaired 't' test applied) for 0 -30 day follow up is given in Table no. 11

Table 11 Comparative effect of treatment on Hb% in trial group and control group

Groups	Mean Difference	Combine S.D.	S.E.	T cal	P	t table
T-C	0.104	0.5155	0.1330	0.78	>0.05	2.05

When Both the groups were compared for rise in Hb%, it was found that there is total difference of 0.104gm% in Hb with calculated 't'value 0.78 and table value of 't' is 2.05 which means t calculated< t table. So calculated 't' value is insignificant. Hence both group shows equal rise in Hb% for 0 -30 day follow up.

Comparative effect of treatment on Hb% in trial group and control group (Unpaired 't' test applied) for 30 -60 day follow up given in table no. 12

Table 12 Comparative effect of treatment on Hb% in trial group and control gro

Groups	Mean Difference	Combine S.D.	S.E.	T cal	P	t table
T-C	0.19	0.7050	0.1819	1.06	>0.05	2.05

When Both the groups were compared for rise in Hb%, it was found that there is total difference of 0.19gm% in Hb with calculated 't'value 1.06 and table value of 't' is 2.05 which means t calculated< t table. So calculated 't' value is insignificant. Hence both group shows equal rise in Hb% for 30 -60 day follow up.

CONCLUSION

- Iron deficiency Anaemia can be co-related with *Panduroga*.
- *Dhatryaavleha* and Oral Iron supplementation will be commonly given in the treatment of *Panduroga*.
- Most of the patients of Iron deficiency are of the age group of 4-8 years and most of the patients are belongs to female sex.
- Statistically *Dhatryaavleha* and Syrup Orofer showed equal effects in rising Hb% .
- But it was observed that Syrup Orofer was better than *Dhatryaavleha* in rising Hb%.
- Statistically *Dhatryaavleha* and Syrup Orofer showed equal effects in improvement in subjective parameters.
- Patients treated with *Dhatryaavleha* had less adverse effects than Syrup Orofer.
- Hence it can be concluded that *Dhatryaavleha* is proved to be effective and safe in Panduroga.

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