

AN OPEN LABEL RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF DHATRI LOHA AND AYA CHENDOORAM (SIDDHA MEDICINE) IN THE MANAGEMENT OF PANDU ROGA (IRON DEFICIENCY ANAEMIA)

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Abstract

Ayurveda and siddha medicine describes pandu roga as an illness which occurs due to lack of hemoglobin. It occurs mainly due to deficiency of iron intake in food source. Pandu roga is a Varnopalakshita Vyadhi of Rasavaha Srotas characterized by pallor of body Alaparaktata, Alpamedaska, Nissarata, Shitilindriya & vaivarnya which strikingly resembles with “Anaemia” of modern science ‘A reduction below normal in the concentration of Hemoglobin or red blood cells in the blood’ there is a reduction in oxygen transporting capacity of blood. Indian system is one of the oldest systems of medicine in the world. Ayurveda and siddha is indigenous system of medicine is an integral part of Indian culture. It has established its position as a unique health care system with a holistic approach to any complex health conditions. The main aim of Ayurveda and siddha is to maintain the health of the healthy person and to cure the illness of a sick person. The ancient acharyas from centuries used herbal and mineral products for preventing and curing various ailments. Both Ayurveda and siddha is based on its own unique and original concepts and fundamental principles of panchamahabhuta that sustenance of a healthy body depends upon the proper function of Dosha, Dhatus and Mala. Dhatri loha (Ayurveda medicine) and Aya chenduram (siddha medicine) are preparation intended to use in pandu roga and proven haematinic action. The present study intends to clinical evaluation the therapeutic effect of the formulation in patients of pandu roga.

Keywords: Dhatri loha; Aya chendooram; Iron Deficiency Anaemia, Pandu

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INTRODUCTION

Anaemia is public health problem globally affecting both developing and developed countries with major consequences for human health as well as social and economic development. Hence, it is the need of the study to develop medicaments for better management of this condition.

Rakta has been considered as a key factor for the Jeevana, Prinana, Dharana and Poshana karma (nourishments) of the body¹. Many a times it is seen that Rakta (blood) gets vitiated by Doshas, mainly by Pitta dosha as Rakta is Pittavargiya (type of pitta) and disease like Pandu (anaemia) appear. In Ayurveda, Pandu is considered as a specific disease with its own pathogenesis and treatment.^[2] Thus an attempt has been made to study disease Pandu Roga according to Ayurvedic text in the parlance of Iron Deficiency Anaemia. In modern medicine, there is good treatment for Anaemia with considerable result but that is only for acute deficiencies Anaemia's. No significant therapy is there for Chronic Anaemia which occur due to metabolic defects. Indian medicines can provide better management of this area. Anaemia is defined as a deficiency in the blood's ability to supply tissues and organs with adequate oxygen.

India is one of the countries having highest number of cases of Anaemia in world over 90% of Indian women adolescent girls and children are anaemic. Anaemia adversely affects mental and motor development. So controlling the iron deficiency anaemia is necessary to improve the quality of life.

Snehana (oleation), Urdwa and Adho Shodhana (purification procedures) with Teekshna (potent) drugs. Shamana Chikitsa (palliative treatment) are the main lines of treatment adopted by our Acharyas in the management of Pandu Roga.

Different modalities of treatments, diet plans, iron supplements etc; have emerged to manage this condition. Ayurveda and Siddha advocate the treatment of Pandu with many herbal and herbo-mineral combinations and same line of treatment but narrated in different language. Ayurveda is narrated in Sanskrit and Siddha is narrated in Tamil.

MATERIALS AND METHODS

Sources of data

1. Literary source

All the Ayurvedic classics, contemporary Ayurvedic literatures, modern texts and internet sources mentioning about the condition, medicine and administration were reviewed and documented for the intended study.

2. Sample source

Diagnosed cases of Pandu were selected from OPD and IPD of Karnataka Ayurveda Medical College Hospital and also from referral sources and special medical camps were conducted for the purpose:

3. Pharmaceutical sources

Aya chendooram was selected as the trial drug. This was prepared at the teaching pharmacy attached to Karnataka Ayurveda Medical College, Mangalore. Dhatri loha was purchased from Dhootapapeshwar

Raw drugs for the Aya chendooram preparation were procured from authentic sources in and around Mangalore.

The ingredients of Dhatri loha^[3] and Aya chendooram^[4] are tabulated in Table 1 and Table 2 respectively.

Table 1: Ingredients of Dhatri loha

Sl.No.	Name of the drug	Botanical name
1	Amalaki	<i>Emblca officinalis</i>
2	Loha	Ferrum
3	Shunti	<i>Zingiber officinale</i>
4	Maricha	<i>Piper nigrum</i>
5	Haridra	<i>Curcuma longa</i>

Table 2: Ingredients of Aya chendooram

Sl.No.	Name of the drug	Botanical name
1	Loha	Ferrum
2	Haritaki	<i>Terminalia chebula</i>
3	Amlaki	<i>Emblca officinalis</i>
4	Bibitaki	<i>Terminalia bellirica</i>
5	Guduchi	<i>Tinospora cordifolia</i>
6	Jambu	<i>Syzygium cumini</i>
7	Pala charu (Key lime)	<i>Citrus aurantifolia</i>

Method of collection of data

a) Sample size

A minimum of 60 patients fulfilling the diagnostic and inclusion criteria of either gender were selected for the clinical study. They were randomly assigned into two groups, Group A and Group B with 30 patients each. Group A: 30 patients were administered Dhatri loha

Group B: 30 patients were administered Aya chendooram.

b) Inclusive criteria

Patients presenting with lakshanas (signs and symptoms) of pandu roga.
Haemoglobin percent >7 to <12g/dl.
Patients of either sex aged between 16-60 years

c) Exclusive criteria

Age above 60 years and below 16 years.
Haemoglobin per-cent<7g/dl in both males & females.

Pandu associated with any other systemic disorder interfering with the treatment like

- 1) Anaemia resulting to acute or chronic blood loss
- 2) Anaemia in pregnancy
- 3) Anaemia resulting underlying chronic disease like Rheumatoid arthritis, hepatic cirrhosis, malignant diseases.

Design of the study

Intervention

The patients of group A treated with Oral administration of Dhatri loha (250 mg) twice a day after food for 30 days with luke warm water.

The patients of group B treated with Oral administration of Aya chendooram (250 mg) twice a day after food for 30 days with luke warm water.

Study duration

Treatment duration: 30 days

Observation period: Before treatment (0 day) and after treatment (31 day) after follow up (40 day)

Total study duration-40 days

Assesment Criteria

Assessment criteria were made by subjective parameter (Table 3) and objective parameter.

Objective Parameter

Objective parameters will be assessed on the basis of values obtained.

1. Hb% - Male 14.0 g/dl to 17.4 g/dl.
Female 12.3 g/dl to 15.3 g/dl.
2. Total count. - 4000-1000 cells/cumm
3. Differential count: Neutrophils -45-65%
Lymphocytes-20-30%
Eosinophils- 01-06%
4. M.C.V: 80 – 100 fl
5. PCV: 37-54%
6. Peripheral smear
NORMOCYTIC NORMOCHROMIC-0
NORMOCYTIC HYPOCHROMIC- 1
MICROCYTIC HYPOCHROMIC- 2

Statistical analysis

For the statistical analysis, the data obtained in both the groups were recorded. Presented in tables, diagrams and graphs. Statistical analysis was done with IBM spss software version 20. The following statistical tests are used for event of subjective and objective parameters:

- a) Assessment of subjective parameters within the group (after treatment and after follow up) - Wilcoxon signed rank test
- b) Assessment of subjective parameters between the groups-Mann-Whitney U tests

c) Assessment of objective parameters within the group (after treatment and after follow up)- Paired t test

d) Assessment of objective parameters between the groups – Independent sample t test

OBSERVATION

The patients were assessed on different parameters for obtaining the effect of therapies. All clinical signs and symptoms were assessed on the basis of scoring given to them. The general observations pertaining to the Age, Sex, Occupation, Religion, Diet etc. of 60 patients of Pandu recorded in this series observed here.

Age: The age group selected for the study was 18-60 yrs. This was to maintain the uniformity in dosage of drug. On the observation of age wise distribution of 60 patients of Panduroga, it was found that 75% were between the age group of 18-30 years.

Gender: The incidence of gender showed that the Females 75% (45 patients) were the greater sufferers of the disease when compared to Men 25% (15 patients).

Religion: There were 76.36% (46 patients) who reported from Hindu religion with 13.28% (8 patients) from Muslim community and 9.96% (6 patients) from Christian community.

Occupation: The highest incidence observed was in students (48%). The second highest was in office workers (28%) and Third housewives (24%),

Habitat: Rural population had a higher incidence of Pandu roga (IDA) than the urban population due to improper food habits and poor standards of living

Table 3: Subjective parameter

Parameters	Score
1) Panduta in twak, nakha, Netravartma, jihva, hastapadata (yellowish discoloration in skin, nails, eyes, tongue, hand and legs)	
Absent	0
In any 2 of these	1
In any 3 of these	2
In any 4 of these	3
In all	4
2) Durbalata (weakness)	
Not present	0
Weakness after doing moderate work, relieved soon	1
Weakness on mild work work, relived later	2
Weakness even in rest	3
3) Hrispandana (palpitation)	
Not present	0
After moderate work relived soon	1
After mild work relieved later & tolerate	2
Even at rest	3
4) Bhrama (tremor)	
Not present	0
Mild without affecting daily activities	1
Mild affecting daily routine	2
Even on sitting or performing daily activities	3
5) Rukshata in Twak, Nakha, Netravartma, Jihva, Hastapadata (dryness discoloration in skin, nails, eyes, tongue, hand and legs)	
Absent	0
In any 2 of these	1
In any 3 of these	2
In any 4 of these	3
In all	4
6) shirasulam (headache)	
Absent	0
Occasional & tolerable	1
Occasional & non tolerable	2
Constant & non tolerable	3
7) Swasa (dyspnoea)	
No Dyspnoea	0
Dyspnoea present but not affecting daily activities	1
Dyspnoea present affecting daily activities	2
Dyspnoea present even in rest	3
8) Pindikodweshtanam (catching pain in calf muscle)	
Absent	0
Cramps after 1 hour of walk	1
Cramps after 1/2 hour walk	2
Cramps after 10 minutes walk	3

Socio Economical Status: Middle class people have been recorded more in this study. Lower 8.3% (5 patients), Middle 84.66% (51 patients), Upper 6.64% (4 patients).

Food Habits (Diet): In the present clinical trial out of the 60 patients, 13.28% (8 patients) were pure vegetarians and 86.32% (52 patients)

Alcohol: Out of 60 patients 19 patients had habit of consuming alcohol among them few are taking the alcohol on daily basis others were occasionally taking. Even small of alcohol also disturbed the treatment and also causative factor of nidana.

Deha Prakruti: The deha prakruti of the patients were also assessed, after considered their major physical, psychological and behavioral features. All patients had Dwandwaja prakruti among total 60 patients. 18 patients were vatapitta 11 patients were pittakapha 7 patients were kaphavata 10 patients were vata kapha 8 patients were pittavata 6 patients were kaphapitta.

RESULTS

Comparative results of Group A and Group B after follow up (Subjective parameters), Comparative results of Group A and Group B follow up (objective parameter) and Over all response of Group A and Group B follow up are tabulated in Table 4, Table 5 and Table 6 respectively.

DISCUSSION

Dhatri loha is a herbo mineral preparation. Mode of action of Dhatri loha are as follows: Amalaki and Loha are main ingredients in this yoga and hence the name Dhatri loha mentioned in Bhaishajya Ratnavali.

Action of the medicine mainly depends upon its constituents like Rasa (taste), Guna (properties), Veerya (potency), Vipaka (post digestion), Prabhava (peculiar action) etc.

Rasa

Amalaki is an Amla rasa pradhana (predominance of sour taste) and can increase Raktha (blood) and hence in Rakthalpatha (anaemic condition), Amla preeti (fond of sour taste) is seen. It also being a rich source of Vit. C helps in absorption of iron.

Hence it is used in Anaemia along with iron compound Shunti, Marica and Haridra are Katu rasa pradhana dravyas (predominance of pungent taste) which can promote Agni (digestive fire) by their Deepana (kindles digestive fire) & Pachana (digestive) properties which can nullify the Agnimandhya (indigestion), Aruchi (loss of taste) like laksanas (signs and symptoms) of Pandu roga. They also provide an acidic media for the better absorption of Loha bhasma (Iron).

Guna

Laghu (light), Ruksha (dryness), Snigdha gunas (unctuousness) of dravyas can revert back the conditions like Dhatu Shaithilya (Flaccidity of body constituents), Gourava (heaviness).

Virya

Most of dravyas of yoga have Sheeta Virya (cold in potency).

Vipaka

Most of dravyas have Madhura Vipaka (sweet in post digestive) viz; Amalaki, Shunti, Loha bhasma, Madhura, Sheeta guna are Bala Varnakara (strengthening), Dhaturvardhaka (promotes body tissues), Preenana and Jeevana (nourishment).

Prabhava

Pramathya property of Marica may help in clearing the srotas (channels). Haridra acts as a Srothoavarodha (clears the channels).

Table 4: Comparative results of Group A and Group B after follow up (Subjective parameters)

Subjective Parameters	GROUP A		GROUP B	
	Mean	±SD	Mean	±SD
Panduta	0.23	0.430	0.10	0.305
Durbalata	0.10	0.305	0.17	0.379
Hridaspandana	0.07	0.254	0.03	0.183
Bhrama	0.03	0.183	0.17	0.379
Rukshata	0.07	0.254	0.17	0.379
Shirasulam	0.03	0.183	0.10	0.305
Swasa	0.07	0.254	0.03	0.183
Pindikoswetanm	0.37	0.490	0.10	0.305

Table 5: Comparative results of Group A and Group B follow up (objective parameter)

Objective Parameters	GROUP A		GROUP B	
	Mean	±SD	Mean	±SD
HB% (gm)	9.85	0.82	10.35	0.74
Total Count	8293.33	623.08	8716.67	777.30
Neutrophils	59.73	2.79	60.13	2.98
Lymphocytes	35.87	2.91	37.67	3.26
Eosinophils	2.87	0.90	3.23	0.77
M.C.V.	81.60	5.08	83.90	5.13
P.C.V.	35.80	2.03	36.69s	2.29
PBS (Blood Picture)	0.07	0.25	0.03	0.18

Table 6: Over all response of Group A and Group B follow up

Grouping	Response	GROUP A		GROUP B	
		No. Of Subjects	%	No. Of Subjects	%
(0%-25%)	Poor Response	0	0%	0	0%
(25%-50%)	Mild Response	0	0%	0	0%
(50%-75%)	Moderate Response	2	7%	3	10%
(75%-99%)	Marked Response	24	80%	17	57%
(>99%)	Complete Response	4	13%	10	33%
Total		30	100%	30	100%

Haridra is Krimighna (anthelmintic) and Loha bhasma can directly increase the Raktha dhatu (Hematinic effect).

Amalaki can act as Rasayana (Rejuvenation) to prevent Ojokshaya (reduces vigor).

Dosaghnata: All the ingredients of yoga are Tridosahara and Kapha Vatashamaka. As we know, one among Kaphaja vyadhis is Pandu roga. Vitiated Kapha in Twacha (skin) produces Shweta avabhasata (pale) and vitiated Vata in the body is responsible for producing

lakshanas of Pandu roga like Karshya (emaciation), Dhatu Kshaya (depletion of tissues), Shaithilya (looseness) etc., to nullify the Kapha and Vata these dravyas are very much important. Hence by considering above points Dhatriloha might have produced beneficial effect in the signs and symptoms of the disease as well as increasing the hemoglobin concentration.

Aya Chendooram is a herbo-mineral preparation Mode of action of Aya Chendooram are as follow:

Loha (Aya) and jambu Swarasa and nimbu swarasa (juice of *Syzygium jambolanum* and Key lime) are main ingredients in this yoga and hence the name Aya Chendooram mentioned in Siddha literature kannusamiyam vaithyasegaram. Action of the medicine mainly depends upon its constituents like Rasa, Guna, Veerya, Vipaka, Prabhava etc.

Jambu - rasa is kashaya (astringent), Madura (sweet), amla (sour). As rakta is the seat of pitta, kashaya and Madura decreases pitta and hence every impurities in the blood is relieved by the kashaya rasa has sthambana (binding nature) property by which the Fe content can bind. Jambu is ruksha guna (dryness) it is again pitta hara in nature. It has the dosha karma like kapha pitta hara.

Nimbu is deepana pacana in nature so it clears Aamathwa (undigested materials) and makes the dhatuagni proper. It is found that citric acid has the property to increase absorption of iron, which will reduce anemic condition. Both nimbu and jambu has krimighna (anthelmintic) property by which the intestinal worms eliminated, worm infestation is one of the main causes of Anaemia.

There is a possible chance of absorption of iron from the cast vessel because of the properties of citric acid and again made into 1 puta (incineration) due to micro particles (Rekha pooranativam) it easy absorbed in the body

which may be a reason for the better result of this preparation in iron deficiency Anaemia.

Females are mostly affected by Pandu Roga than males. Marital status, religion, Social status bear no relation in causation of Pandu Roga. Sedentary life style, and faulty dietary habits are main contributing factors in the establishment of the disease. Tendency towards sedentary life style and faulty dietary habits, leads to vitiation of Pitta and Raktha leading to Pandu roga. Contributory factors are mainly related with Pitta and Raktha vitiation. Dominancy of Pitta Dosha, Raktha Dhatu Dusti, Rasavaha and Rakthavaha Srotodushti in the pathogenesis of Pandu roga is confirmed by the study. Pandu Roga is a disease characterized by Panduta, Durbalata, Hrispandana and Rukshata of the body.

Statistical data also showed significant result. Both the trial drugs are effective in increasing the Hemoglobin percentage. The Hb% with $P < 0.001$ which is statistically significant in both groups.

CONCLUSION

Conclusion can be drawn on the basis vataja Pandu Nidana, purva rupa and Samprapti, that it can be correlated with Iron deficiency Anaemia. Dhatu apakarshana and Ojo dushti is a habitual appearance of the disease. On the basis of result of the therapy it can be concluded Dhatri loha and Aya chendooram has provided relief in the chief complaints like Panduta, Durbalata, Hrispandana, Bhrama, Rukshata, shirasulam, Swasa, Pindikodweshtanam. It was effective in increasing the Hemoglobin percentage. The Hb% with $P < 0.001$ which is statistically significant in both groups. The current study was carried on small sample for a partial time and it showed hopeful results. However to be more confirmative further study should be conducted on large sample for longer duration with different Anupana. There is no significant difference in the effect of Dhatri loha and Aya chendooram in Pandu roga.

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