

**A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF *TANDULIYAKA* IN *GARBHINI PANDU* W.S.R. TO ANAEMIA DURING PREGNANCY****Singh Ritu^{1*}, Singh D.C.², Tomar Pravesh³**¹M.D. Scholar, ²Professor and H.O.D., P.G. Department of Dravyaguna, Rishikul Campus, Uttarakhand Ayurved University, Uttarakhand, India.³Associate Professor, P.G. Department of Prasuti Tantra evam Stri Roga, Rishikul Campus, Uttarakhand Ayurved University, Uttarakhand, India.**ABSTRACT**

Under-nutrition and micronutrient deficiencies are widespread and affect mainly women and children. To address these problems, increased consumption of leafy vegetables is promoted as sources of both micronutrients and bio-active compounds. Widely promoted leafy vegetables include *Amaranthus* sp., Species of this genus are used as pseudo-cereals in Europe and America, and are mostly planted as vegetables in Africa. *Amaranthus* has been rediscovered as a promising food crop mainly due to its resistance to heat, drought, diseases and pests, and the high nutritional value of both seeds and leaves. Leaves are rich in proteins and micronutrients such as iron, calcium, zinc, vitamin C and vitamin A. Pregnancy induces some physiological changes that often confuse the diagnosis of several disorders and the assessment of the suitable treatments. This is especially true in case of anaemia. The World Health Organization estimates that 58% of pregnant women in developing countries are anaemic. The two most common causes of anaemia during pregnancy are iron deficiency and acute blood loss. Iron deficiency anaemia is the most common nutritional disorder in the world that affects particularly women of reproductive age. In the present study *Amaranthus* capsules showed significant improvement in terms of subjective parameters like *Panduta*, *Hrid-drava*, *Shrama*, *Swasa*, *Aruchi*, as well as objective parameters like Hb%, MCV, PCV, RBC etc. This study has revealed that *Amaranthus* capsules provided statistically significant improvement in the cardinal features of *Garbhini pandu* as well as it has showed good effect on *Jatharagni* and nourishment of pregnant women and foetus without any side-effects, due to its properties like *Deepana*, *Pachana*, and high nutritional value.

KEYWORDS: *Garbhini pandu*, *Amaranthus viridis*, IDA, Nutritional deficiency.**INTRODUCTION**

In present day unwholesome food habits are influencing deficiencies of vital nutrients and leads to nutritional disorders. The disease *Pandu roga* that is dealt in all Ayurvedic texts with its treatment which is very much similar to anaemia in later period. *Pandu*, is a disease characterized by pallor of body which strikingly resembles with 'Anaemia' of modern science, reduction in number of Rbcs per cumm of blood and quantity of Hb resulting in pallor like other symptoms.

Rakta has been considered as a key factor for the *Jeevana*, *Prinana Dharana* and *Poshana karma* of the body. Many a times it is seen that *Rakta* gets vitiated by *Doshas*, mainly by *Pitta dosha* as *Rakta* is *Pittavargiya* and disease like *Pandu* appear^[1]. In Ayurveda, *Pandu* is considered as a specific disease with its own pathogenesis and treatment (Cha.Chi.16,Su.Utt. 44). Though there is no direct reference of *Garbhini pandu* in Ayurvedic classics but term *Varna hani* in *Garbhini* resembles closely *Panduroga*, which is considered as *Pitta Dosha pradhan*. *Acharya Charaka* in *Sharira sthana* has explained about *Bala varna hani* of *Garbhini* in 6th month of pregnancy. It can be considered as reference for *Garbhini pandu* ^[2]. There is a significant role of *Pitta* in *Varna uttaptti*, and *Acharya Charaka* has quoted that *Pitta dosha* is very important substance in natural

colour of body, and if *Pitta* gets vitiated the normal color of body and other sites of body turns into *Pandu*, *Haridra* and *Haritadi varnas*. ^[3]

The prevalence of anaemia among women has been reported to be 50% while among men it is 44.3% but prevalence of mild anaemia was higher (men 29.3%; women 32%) than moderate and severe anaemia. However younger women (<30 years) have been shown to have higher prevalence of anaemia (55%)^[4]. According to World Health Organisation (WHO), If the prevalence of anaemia at community levels is >40%, then it should be considered a public health care problem of high magnitude^[5]. Also globally >468 million non-pregnant women suffer from anaemia; of these 388 million are from developing regions of the world and rest of them are from Europe and the America ^[6]. In a study conducted by Ansari et al, in 65.2% women with a history of pregnancy, 24.71% females had their first pregnancy before the age of 20 years, 68.96% females were multipara and 62.06% of those with an inter-pregnancy interval of <1year had IDA. The researchers also reported that 34.8% patients with no history of pregnancy had iron deficiency anaemia.

Iron Status During Pregnancy: Setting the stage of mother and infant- Supplementation with iron is generally

recommended during pregnancy to meet the iron needs of both mother and fetus. When detected early in pregnancy, IDA is associated with a >2-fold increase in the risk of preterm delivery. During the third trimester, maternal anaemia usually is not associated increased risk of adverse pregnancy outcomes and may be an indicator of an expanded maternal plasma volume. High levels of Haemoglobin, Hematocrit and ferritin are associated with an increased risk of fetal growth restriction, preterm delivery, and preeclampsia. While iron supplementation increases maternal iron status and stores, Factors that underlie adverse pregnancy outcome are considered to result in this association, not iron supplements. On the other hand, Iron supplements and increased iron stores have recently been linked to maternal complications (Eg.- Gestational Diabetes) and increased oxidative stress during pregnancy. In Pregnancy, nutrition is used for nourishment of *Garbhini*, her foetus, placenta and breast. So nutritional requirements are high during pregnancy [7]. Which if not fulfilled, lead to deficiency disorders like Iron deficiency anaemia (I.D.A).

Material and Methods

Study Design- Open level, controlled clinical trial with pre and post test design.

Drug Source- The required herbal formulation was prepared specially for the study in Rishikul Campus, Haridwar, UAU.

Method of collection of Data

Drug Source: *Tanduliyaka* plant was collected from Rishikul campus and from Rajrajeshwari herbal garden.

Patient source: Pregnant women suffering from *Panduroga* (IDA) were registered from OPD and IPD of

Rishikul Ayurvedic College and District Women hospital Haridwar.

Sample Size: Minimum of 40 pregnant women fulfilling the diagnostic criteria as well as inclusion criteria of *Panduroga* irrespective of their cast, religion, socio-economic status, education, etc. were selected for the study.

Preparation of Tanduliyaka Ghan

Ghana Kalpana, a second derivative preparation of *Kwatha Kalpana*, is one of the extraction methods in which water soluble material is extracted by *Kwatha* method and reheated till it is converted into concentrated solid form.

Method of Preparation

The authenticated drug (*Amaranthus viridis*) was crushed to a coarse particle separately and then mixed thoroughly with 8 parts of water in a stainless steel container and then continuous mild heat was applied until it was reduced to one-fourth of its initial quantity.

During the heating process, continuous stirring was done to facilitate the evaporation and avoid any deterioration due to burning of materials. After a desirable reduction in volume was achieved, the *Kwatha* was filtered through single folded cotton cloth and collected in a separate vessel.

Then, the *Kwatha* was boiled again over slow fire on a gas stove, maintaining the temperature between 90°C and 95°C till a semisolid consistency is obtained. As the water evaporates, the viscosity of the extract increases, resulting in *Ghana* form. Then the *Ghana* was dried in dryer at the temperature of 65°C.

After this powder is prepared from dried *Ghana*. Then this powder is filled into capsules of 500mg.

Figure 1: Step-wise preparation of Amaranthus Ghana

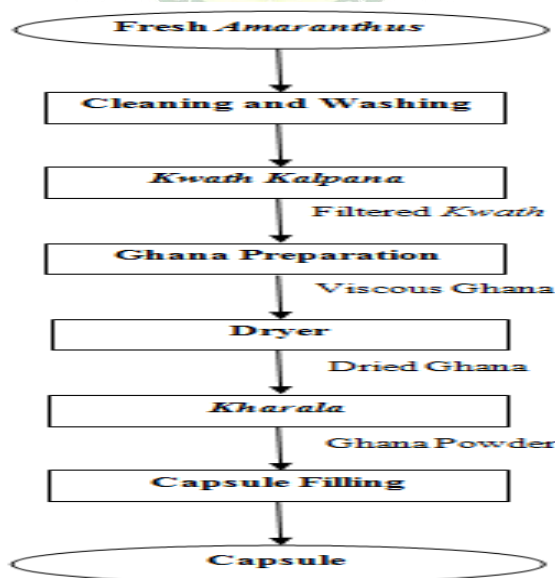


Table 1: Testing results of Amaranthus Ghana

Test parameters	Results	Test method
Total Ash Value	29.13%	API 2008
Acid insoluble Ash	1.70%	API 2008
Water soluble Ash	22.68%	API 2008
Loss on drying	7.48%	API 2008
pH Value (5% w/v)	5.16	API 2008
Fat Content	0.504%	API 2008

Water soluble Extractive	92.46%	API 2008
Alcohol soluble Extractive	43.88%	API 2008
Folic acid Content	20 mg /100 gm	In House
Iron content	61.58 mg/100 gm	In House
Calcium Content	0.44% w/w	In House
Sodium Content	2.867 mg/ 100 gm	In House
Potassium Content	40.002mg/100 gm	In House
Zinc Content	5.122mg/100gm	In House
Chromium Content	0.00364mg/100gm	In House
Magnesium Content	0.56 % w/w	In House

Selection criteria**Diagnostic criteria****Complete blood culture**

- 1) T.L.C.
- 2) D.L.C.
- 3) E.S.R.
- 4) ABO Rh
- 5) Hb % - Less than 4 million/cumm
- 6) PCV - Less than 30%
- 7) MCV - Less than 75 μ m³
- 8) MCH - Less than 25 pg
- 9) MCHC- Less than 30%
- 10) VDRL
- 11) HbsAg
- 12) Serum Fe (Normal value 50-150 μ g/dl)
- 13) TIBC (Normal value 300-360 μ g/dl)
- 14) Serum Ferritin (Normal value 50-150 μ g/dl)
- 15) Red cell porphyrin level (Normal value 30 μ g/dl)
- 16) Stool testing
- 17) Urine (routine and microscopic)

Inclusion Criteria

- ❖ Fulfilling the diagnostic criteria.
- ❖ Age group between 20-35 years.
- ❖ Gestational age between 16 weeks to 24 weeks.
- ❖ Primigravida
- ❖ Haemoglobin below 10gm% and above 6gm%.
- ❖ Blood picture with microcytic hypochromia and normocytic hypochromia.

Exclusion Criteria

- ❖ Cases of Anaemia other than iron deficiency anaemia like thalassaemia, Sickle cell anaemia, Pernicious anaemia.
- ❖ Haemolytic anaemia, Aplastic anaemia.
- ❖ Anaemia associated with bleeding piles and other bleeding disorders.
- ❖ Multiple pregnancy.
- ❖ High risk cases of Preeclampsia, Gestational diabetes, Metabolic disorders, Diabetes, Jaundice etc.
- ❖ Other medical disorders.
- ❖ Drug allergy.

Assessment Criteria

All the data was collected and documented as a detailed case performa. Assessment of the disease was done adapting standard methods of scoring. Subjective and objective parameters were analysed statistically.

Subjective parameters

Dourbalya (generalized weakness)

Aruchi (Loss of appetite)
Arohanayasa (Exertional dyspnoea)
Angamarda (Fatigue)
Hridrava (Palpitation)
Shiroruja (Headache)
Pandutva of Netra, Nakha (Pallor)
Rukshangata (Dryness)
Shotha (oedema)
Alasya (Lassitude)

Objective parameters

Haemoglobin (Hb%)
 Red blood cell count (RBC Count)
 Haematocrit (Hct/PCV)
 Mean corpuscular volume (MCV)
 Mean corpuscular haemoglobin (MCH)
 Mean corpuscular haemoglobin concentration (MCHC)

Grading of subjective parameters

Changes in patients status were noted and following points were taken into considering for assessment of results. To assess the effect of therapy objectively, all the signs and symptoms were given scoring pattern depending upon their severity as below:

1. Panduta

In - *Twaka, Nakha, Netravartma, Jihva, Hastapadatala*

Absent - 0

In any 2 of these - 1

In any 3 of these - 2

In any 4 of these - 3

In all - 4

2. Daurbalyata

Not Present - 0

After heavy work, relieved soon & tolerate - 1

After Moderate work relieved later & tolerate - 2

After little work relieved later - 3

After little work relieved later but beyond tolerate - 4

3. Hridspandnam

Not Present - 0

After heavy work, relieved soon & tolerate - 1

After Moderate work relieved later & tolerate - 2

After little work relieved later - 3

After little work relieved later but beyond tolerate - 4

Hridayaspandanam even in resting condition - 5

4. Bhrama

Not Present - 0

After heavy work, relieved soon & tolerate - 1

After Moderate work relieved later & tolerate - 2

After little work relieved later - 3
 After little work relieved later but beyond tolerate - 4
 Bhrama even in resting condition - 5.

5. Shunakshikuta shotha

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

6. Rukshata

In - *Twaka, Nakha, Netravartma, Jihva, Hastapadata*
 Absent - 0
 In any 2 of these - 1
 In any 3 of these - 2
 In any 4 of these - 3
 In all - 4

7. Swasha

Not Present - 0
 After heavy work, relieved soon & tolerate - 1
 After Moderate work relieved later & tolerate - 2
 After little work relieved later - 3
 After little work relieved later but beyond tolerate - 4
 Swasha even in resting condition - 5

8. Aruchi

Normal instinct of taking food - 0
 Person even dislikes the touch or smell of food - 1
 Though the person is hungry he had dislike for food
 Due to fear, anger etc - 2
 Person doesn't like to take food due to *Sharira/Manas*
doshas - 3

9. Pindikodweshtanam

Absent - 0
 After heavy work - 1
 After moderate work - 2
 Only at night but beyond tolerate - 3
 Whole day, severe, require medicine - 4

10. Jwara

No - 0
 Occasional - 1
 Daily once - 2
 Constant - 3

Table 2: Grading of Objective parameters

Parameters	Grading
1. Erythrocyte Count	
> 4.2 million	Grade 1
4.2- 5.4 million	Grade 2
< 4.2 million	Grade 3
2. PCV	
<33%	Grade 1
33%- 38%	Grade 2
>38%	Grade 3
3. Mean Corpuscular Volume	
> 70-90 cu μ / cell	Grade 1
70-90 cu μ / cell	Grade 2
< 70-90 cu μ / cell	Grade 3

Observations

Out of 40 patients registered for the study maximum patients (56.66%) were in age group 18-25 years. And 56.66% were Muslims. Out of 40 patients 50.00% belonged to lower class. 56.66% were house wives. 36.66% were completed their secondary education. 51.00% belonged to urban habitat. 33.33% had *Tikshnagni*. Whereas 36.66% had *Madhyama Koshtha*. 46.66% were having disturbed sleep. 43.33% were performing mild physical work. 73.33% were not doing any exercise. 43.33% had *Vata-Pittaja Prakriti*. 30.00% had joyful emotional status. 53.33% were having *Madhyam vyayam shakti*. And 46.66% had regular bowel habit. All registered patients were having complaints of *Daurbalya, Aruchi, Hridrava* and *Panduta*.

RESULTS

Patients suffering from *Garbhini pandu / IDA* were treated with two *Amaranthus viridis* capsules 500mg thrice a day with lemon water for 90 days in this randomized controlled clinical trial study.

Table 3: Demographic Presentation

S.No.	Observation	Maximum	No. of patients	Percentage
1.	Age	<i>Vivardhaman</i>	17	56.66
2.	Socio-economic	Lower class	15	50.00
3.	Religion	Muslims	17	56.66
4.	Occupation	House wife	16	53.33
5.	Appetite	Poor	11	36.66
6.	<i>Kostha</i>	<i>Madhyam</i>	11	36.66
7.	Nature of work	Mild	13	43.33
8.	Sleep Pattern	Disturbed	14	46.66
9.	<i>Agni</i>	<i>Tikshna</i>	10	33.33

Table 4: Observations of Clinical features

S.No.	Clinical features	No. of patients	Percentage
1.	<i>Panduta</i>	09	30%
2.	<i>Daurbalya</i>	08	26.66%
3.	<i>Hridspandana</i>	03	10%
4.	<i>Shrama</i>	03	10%
5.	<i>Swasa</i>	01	3.33%
6.	<i>Aruchi</i>	06	20%

Table 5: Quantitative analysis of Cap. A.V (*Amaranthus viridis*)

Parameter (n=14)	Mean		X	%	SD	SE	't'	P Value
	BT	AT						
Haemoglobin	8.073±1.089	9.520±0.9435	1.447	17.923	0.769	0.2056	7.036	<0.0001
RBC	2.733±0.4577	2.467±0.5164	0.2667	9.759	0.4422	0.1182	2.256	< 0.05
PCV	1.467±0.6399	1.533±0.5164	-0.06667	4.545	0.5736	0.1533	0.4350	>0.05
MCV	2.600±0.5071	2.400±0.5071	0.2000	7.692	0.3990	0.1069	1.871	>0.05

Table 6: Qualitative analysis of *Amaranthus viridis* capsule

Parameter (n=14)	Mean		X	%	SD	SE	't'	P Value
	BT	AT						
<i>Panduta</i>	2.333±0.8165	0.6667±0.4880	1.667	71.453	0.6993	0.1869	8.919	<0.0001
<i>Daurbalya</i>	1.933±1.100	0.6667±0.4880	1.267	65.546	0.9286	0.2482	5.104	<0.001
<i>Hridspandana</i>	1.333±0.8165	0.4667±0.5164	0.8667	65.019	0.6181	0.1652	5.245	0.0001
<i>Rukshta</i>	1.200±1.146	0.4000±0.5071	0.8000	66.667	0.8325	0.2225	3.595	<0.01
<i>Aruchi</i>	0.4000±0.5071	0.000	0.4000	40.000	0.4897	0.1309	3.055	<0.01
<i>Swasa</i>	1.467±1.246	0.4000±0.6325	1.067	72.73	0.8538	0.2282	4.675	<0.001

Statistical Analysis

The information gathered on the basis of above observations was subjected to statistical analysis using Graph Pad InStat Software Version 3.10. As the criteria selected for analysis were parametric hence 'paired t test' was applied for statistical improvement analysis in single group and 'unpaired t test' for statistical status of intergroup differences of clinical features.

The obtained results were interpreted as:

Not significant $P > 0.05$

Significant $P < 0.05$

Very Significant $P < 0.01$

Extremely significant $P < 0.001$

Effect on Subjective and objective parameters

In the present study, we gave capsule A.V. to the patients. Results showed statistically significant improvement in both subjective and objective parameters. The effect of the drug leads to improvement of metabolism, RBCs production, minerals consumption in body and relief from the disease. The most important presenting sign of *Pandu roga* is *Panduta* or Pallor where luster of the skin is lost. This sign is the most conclusive sign of the disease because whenever any patient comes across, the thing first observed is the appearance. Regarding the effect of therapy, extremely significant results seen in patients ($p < 0.001$).

The reason of *Daurbalya* may be the debility of *Dhatukshaya*, *Ojakshaya* as well as *Raktalpata*. If we consider it from modern point of view, the cells in the blood are responsible for oxygen supply to body tissues. Regarding the effect of therapy, results were extremely significant ($p < 0.001$).

Ayasaja shwasa is observed in anaemic patients due to *Raktalpata*. But the reason for very significant results may be due to high nutritional value of *Amaranthus*. During pregnancy there is need of extra calories for developing foetus. *Amaranthus* provide nourishment to the body due to presence of other minerals.

The cause of nausea and vomiting in pregnancy is currently unknown. Studies have suggested that nausea and vomiting in pregnancy might be due to hormones,

evolutionary adaptation or psychological causes. The relief was very significant in patients (p value < 0.01). This may be due to high protein and complex carbohydrates present in *Amaranthus* which might be specially helpful in digestion.

The objective parameters i.e. HB%, RBC, MCV, MCHC, results after treatment were found statistically significant. Whereas the results of PCV, WBC, showed statistically insignificant results.

DISCUSSION

Amaranthus has been rediscovered as a promising food crop mainly due to its resistance to heat, drought, diseases and pests, and the high nutritional value of both seeds and leaves^[8]. Quantity and quality of proteins of *Amaranth* are superior to that of wheat. It also contains higher concentration of Folic acid with respect to wheat and its fibers and minerals content are higher to other cereals. Iron-rich (5 times that of wheat) *amaranth* leaves promote coagulation and increase hemoglobin content and red blood cell counts. High dietary fiber content (3 times that of wheat) in this improves digestive health and reduces constipation. It is easily digestible and good for both young ones and elders^[9].

In all types of *Pandu*, *Pitta* is the root cause. The disorders of the pregnant woman should be treated with diet and drugs consisting of *Mridu Virya* (mild potency), *Madhura* (sweet) *rasa*, *Sheeta* (cold) *Vipaka* etc., properties and which are non-contrary to fetus^[10]. This implies that proper nutrition (*Poshya Rasa*) along with *Pitta* pacifying measures are the main stream of management in Ayurveda, a key to treat iron deficiency anemia (IDA) as in modern parlance too. Thus, Ayurvedic management with *Tanduliyaka*, which consisting of all the above-mentioned properties may be considered as an effective way of curing IDA in pregnancy. *Tanduliyaka* is selected for the study because of easy availability, less expensive and *Deepana* (appetizer) *Pachana* (digestive), *Srotoshodhaka* (channel cleanser), *Vishaghna* (one which increases immunity), and *Balya* (one which increases strength).

CONCLUSION

Grabhini pandu (IDA) can be considered as a *Rasapradoshaja vikara*, which is common in *Garbhavastha*

(Pregnancy). In all types of *Pandu*, *Pitta* is the root cause. The *Pitta* predominant *Doshas* are vitiated in *Dhatu*s and as a result of morbidity of *Dosha* and *Dushya* (those affected by *Dosha*), complexion, strength, unctuousness, and other properties of *Ojas* (*Rakta*, i.e. blood or *Ojas*, i.e. immunity) itself get diminished. Nutritional deficiency anemia during pregnancy continues to be a major health problem in India. To eradicate it certain steps can be taken at individual and community level like education of the women as regards anemia, its causes and health implication. *Garbhini* is more prone to suffer from *Pandu*, especially due to *Anuloma-Kshaya* of *Rasa Dhatu*. Normally during pregnancy, erythroid hyperplasia of the marrow occurs, and RBC mass increases. However, a disproportionate increase in plasma volume results in hemodilution (hydremia of pregnancy). Amaranth leaves are rich in easily absorbed calcium, on the teeth and bone growth can play a catalytic role, and can maintain normal myocardial activity, prevent muscle spasms. While rich in iron, calcium, and vitamin K, can promote blood clotting, increasing the oxygen carrying capacity of hemoglobin content and improve, promote hematopoietic function. *Tanduliyaka* capsules were administered with lemon water, as the vehicle (*Anupana*). which enhances the medicinal qualities of the prepared drug, and also helps *Ghana* to reach the deeper tissues. Vitamin C (ascorbic acid) is also a powerful enhancer of iron absorption. Effect of *Amaranthus* capsules showed statistically significant improvement in both subjective and objective parameters. The effect of the drug leads to improvement of metabolism, RBCs production, minerals consumption in body and relief from the disease.

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