



## Clinical Research

## Efficacy of *Triphaladi Avaleha* on *Beejadushtijanya Pandu* (Thalassemia)

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### Abstract

**Background:** Hemoglobinopathies constitute a major public health problem internationally, particularly in the developing world as it has the least resources for coping with the problem. Thalassemia is an inherited single-gene autosomal recessive disorder of the Red Blood Corpuscles (RBCs). Life becomes miserable due to blood transfusion every fortnight, recurrent infections, stunted growth, problems of iron overload, splenectomy, and decreased school performance. Nearly Rs. 1000 Crore is being spent in the treatment of thalassemia per annum. **Aim:** To evaluate the efficacy of *Triphaladi Avaleha* in *Beejadushtijanya Pandu* (thalassemia). **Materials and Methods:** Total 32 patients of age group 1-15 years were registered and randomly divided into two groups. Group A (test drug treated group) and Group B (control group). In Group A, *Triphaladi Avaleha* was given with *Godugdha*, and in Group B, Deferiprone was administered. Assessment was done based on the subjective and objective parameters after 12 weeks of treatment, with a follow-up of 8 weeks. **Results:** The trial drug proved better than the standard control in *Paandutaa* and *Sandhishoola* at a highly significant level and in *Jwara*, *Akshikootashotha* and *Pindikodweshtana* at a significant level. In Group A, five patients (38.46%) showed maximum improvement, five patients (38.46%) showed moderate improvement, two patients (15.38%) had mild improvement. **Conclusion:** *Triphaladi Avaleha* has various properties which help to relieve the signs and symptoms of the disease, as well as decrease the iron overload.

**Key words:** *Beejadushtijanya Pandu*, thalassemia, *Triphaladi Avaleha*

### Introduction

Thalassemia, is the commonest genetic disorder in the world and represent a major health burden worldwide. It is a heterogeneous disorder that is recessively inherited and results from various mutations of the genes which code for globin chains of hemoglobin (Hb) leading to reduced or absent synthesis of globin chains.<sup>[1]</sup> The reduced supply of globin diminishes the production of hemoglobin tetramers, causing hypochromia and microcytosis. Unbalanced accumulation of  $\alpha$  and  $\beta$  subunits occurs because the synthesis of the unaffected globins proceeds at a normal rate. Unbalanced chain accumulation dominates the clinical phenotype. Clinical severity varies widely, depending on the degree to which the synthesis of the affected globin is impaired and the synthesis of other globin

chains is altered, and co-inheritance of other abnormal globin alleles.<sup>[2]</sup> The basic nature of these genetic defects has not been defined. Different types of thalassemia with different clinical and biochemical manifestations are associated with defects in each kind of polypeptide chain ( $\alpha$ ,  $\beta$ ,  $\gamma$ ,  $\delta$ ). In contrast to the hemoglobinopathies, no basic chemical abnormality of hemoglobin species lies behind the thalassemias.<sup>[3]</sup>

In Ayurveda, *Acharya Charaka* described *Beejadushtijanya Vikara*. He explained that specific *Avayava* would be *Vikrita*, if *Doshas* vitiate specific *Beeja* or *Beejabhaga*. Considering this it can be considered as thalassemia. It can also be called *Sahaja* or *Aadibalapravritta Vikara*.

### Thalassemia: A health burden

As per the World Health Organization (WHO) estimates, 4.5% of the world's population are carriers of hemoglobinopathies.<sup>[4]</sup> Over 200 million people in the world and around 20 million in India carry the gene for  $\beta$ -thalassemia. One lakh children are born the world over with the homozygous state for thalassemia.<sup>[1]</sup> Frequency of thalassemia gene in the Indian population varies between 0 and 17% in different ethnic groups, with an average of over 3%.<sup>[4]</sup> The frequency of Thalassemia

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trait is 3-18% in northern India and 1-3% or less in the south. A higher frequency is noted in certain communities, viz. Sindhis, Kutchis, Lohanas, Bhanushalis, Punjabis, Mahers, Agris, Goud Saraswats, Gowdas, etc.<sup>[1]</sup> Also, 10,000 thalassemic children are born every year in India.<sup>[4]</sup> Nearly Rs. 1000 crore is spent for the treatment of thalassemia per annum. One out of every eight carriers of thalassemia worldwide lives in India. This is of particular importance in developing countries like India, where it increases the burden of health care delivery system.<sup>[5]</sup> The mainstay of managing these cases is repeated blood transfusion. Due to frequent blood transfusion, patients develop iron overload which results in growth failure, hypogonadism, diabetes, and hepatic disease. It can be reduced by regular chelation therapy. But iron chelators are costly and have side effects like growth retardation, visual and auditory toxicity, cataracts (with desferrioxamine) and arthropathy, and agranulocytosis (with deferiprone).<sup>[6]</sup>

## Aims and Objectives

To observe the efficacy of *Triphaladi Avaleha* as a hepato-splenoprotective agent, RBCs life prolonger and iron chelator in the management of thalassemia.

## Materials and Methods

### Selection of the patients

Pre-diagnosed patients of thalassemia major attending the OPD of Department of Kaumarabhritya, I. P. G. T. and R. A., Jamnagar, and also, patients registered in the thalassemia ward of G. G. Hospital, Jamnagar, fulfilling the criteria of selection, were enrolled in the study irrespective of age, sex, caste, etc.

### Ethical clearance

The Institutional Ethics Committee gave clearance and approval for the clinical research protocol (PGT/T/Ethics/2009-2010/2157, dated 24/09/2009). Written consent of the parents of each patient was taken before starting the treatment. Basic information of the disease and treatment was given to the patients.

### Criteria for selection of patients

1. Pre-diagnosed patients of thalassemia (diagnosed by the pediatrician of G. G. Hospital, Jamnagar). Patient with the symptoms of fever, fatigue, growth failure, and anemia, advised for routine hematological investigations [Hemoglobin percentage (Hb%), Total Leukocyte Count (TLC), Differential Leukocyte Count (DLC), Erythrocyte Sedimentation Rate (ESR), Packed Cell Volume (PCV), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), and Mean Corpuscular Hemoglobin Concentration (MCHC)], biological investigations [Serum Albumin (S. Alb.), Serum Globulin (S. Glob), Serum Glutamate Oxaloacetate Transaminase (SGOT), Serum Glutamate Pyruvate Transaminase (SGPT), Serum Alkaline Phosphatase (S. Alk. Phosphatase), and Serum Bilirubin (S. Bil.)], and Hb electrophoresis to confirm the diagnosis
2. On the basis of clinical signs and symptoms
3. Age group: 1-15 years.

### Criteria for exclusion of patients

1. Complicated cases (having HIV, HBV, infection, hepatic failure, etc.)
2. Patients with blood transfusion interval for less than 15 days.

### Grouping and posology

Selected patients were randomly divided into two groups by simple random method. Patients of Group A were treated with *Triphaladi Avaleha* and modern medical management-Blood Transfusion (BT); while Group B treated with Modern medical management-BT and iron chelator (deferiprone). The dose of *Avaleha* for a child is not clearly mentioned in the classics. So, the dose was calculated according to Young's formula<sup>[7]</sup> keeping in mind the adult dose of *Avaleha* as 1 *Pala* (48 g)<sup>[8]</sup> with lukewarm milk (50-100 ml) as *Anupana* for 12 weeks duration.

Young's formula:  $(\text{age}/\text{age} + 12) \times \text{adult dose}$

- 1-5 years age group: 4-14 g in three divided doses
- 6-10 years age group: 16-22 g in three divided doses
- 11-15 years age group: 23-27 g in three divided doses.

In Group B, the iron chelator (Tab. Deferiprone) was administered in dose of 75 mg/kg/day for 12 weeks duration. Follow up taken after 8 weeks in both the groups.

### Assessment criteria

A special proforma was prepared to assess the clinical parameters (subjective and objective) with the scores, and to study the etiopathogenesis and response to the given treatment and any complications. The effect of therapy was assessed by counting the scores before and after 12 weeks of treatment.

### Subjective parameters

*Panduta* (pallor), *Hritdravaty* (palpitation), *Daarbalya* (weakness), *Balakshaya* (chronic fatigue), *Akshikootashotha* (puffiness around the orbit), *Jwara* (irregular fever), *Aruchi* (anorexia), *Udarashoola* (abdominal pain), *Pleehavridhi* (splenomegaly), *Yakritvridhi* (hepatomegaly), *Atisara* (loose motion), *Pindikodweshtana* (leg cramps) and *Sandhishoola* (arthralgia).

### Objective parameters

Routine hematological investigations (Hb%, TLC, DLC, ESR, PCV, MCV, MCH, and MCHC) and biological investigations [s. alb, s. glob, SGOT, SGPT, S. Alk. Phosphatase, S. Bil., S. Iron, Serum Total Iron Binding Capacity (S. TIBC), and S. Ferritin] were done in all patients twice, i.e., before and after the treatment schedule. Blood samples for hematological investigations were taken before BT.

### Scoring pattern

The assessment was done based on the improvement in signs and symptoms, following a standard scoring pattern.<sup>[9]</sup>

### Dietary advice

Patients were advised to take low iron diet as well as to follow the restrictions regarding food habits and lifestyle, and to avoid the possible aggravating factors of thalassemia.

### Assessment of total effect of therapy

1. Maximum improvement: >75% improvement
2. Moderate improvement: 50-74% improvement
3. Mild improvement: 25-49% improvement
4. No improvement: ≤25% improvement of clinical signs and symptoms.

## Statistical analysis

Student's "t" test (paired and unpaired) was applied for assessment of the result.

## Selection of trial drug and preparation

The drugs were selected for the present study from *Lohashodhana* and *Lohamarana Gana*,<sup>[10]</sup> drugs used in *Lohasevanajanya Vikara*,<sup>[11]</sup> *Yakrit* and *Pleehaa Vikara*.<sup>[12]</sup>

First of all, *Yavakuta* of all the 11 constituents (each 1200 g) of *Triphaladi Avaleha* was prepared. This was boiled with 16 times of water under low heat and reduced to one-eighth and filtered. Eighteen kilograms of *Sharkara* (sugar) was added to the decoction and again boiled till *Avaleha* is not formed. At this stage, fine powders of *Prakshepa Dravya* (adjuvant) was added. At the end, six kilograms *Madhu* was added after cooling of the *Avaleha* [Table 1].

## Observations

Totally 32 patients were enrolled in the present study, with 16 patients in each group. Of these patients, 24 completed the course of treatment (13 in Group A and 11 in Group B). Eight patients discontinued. Maximum, 15 (46.87%) patients were in the age group of 6-10 years, 21 (65.63%) were males, 24 (75%) were from lower socioeconomic background. Majority of the patients, 25 (78.13%) were diagnosed within the age of 1 year. The number of BT was found to be >100 times in 7 (21.87%)

patients before starting the trial drug. It was found that maximum, 10 (31.25%) patients had BT interval of 15-20 days. Most of the patients, 17 (53.12%) had febrile reactions to BT. Majority of the patients, 16 (50%) were taking iron chelator, i.e., deferiprone. History of consanguineous marriage was found in 9 (28.12%) cases. The parents of 30 (93.75%) patients were investigated with Naked Eye Single Tube Red Cell Osmotic Fragility Test (NESTROFT). On an average, four BTs were given to all the patients of the treated group and six BTs were given to all the patients of the control group during the study.

*Viruddhaashana* and *Adhyashana* were found in 30 (93.75%) patients and 22 (68.75%) patients, respectively. *Lavana Rasa* predominance was observed in 14 (43.75%) patients, while the predominance of *Snigdha* and *Ushna Guna* in diet was observed in 20 (62.5%) and 19 (59.37%) patients, respectively. Most of the patients, 19 (59.37%) liked more of indoor playing activities. Anger was found in maximum 25 (78.12%) patients. *Vaata Pitta Prakriti* was found in 18 (56.25%) patients. *Avara Jarana Shakti* was observed in 20 (62.5%) patients. *Vaata Pitta Dosha* predominance was observed in all selected patients. Majority of the patients, 27 (84.38%) had *Mandaagni*. *Rasavaha* and *Raktavaha Srotodushti* were found in all (100%) patients. Maximum, 21 (65.62%) and 11 (34.38%) patients had *Medavaha* and *Asthivaha Srotodushti*, respectively. *Panduta*, *Daarbalya*, *Yakritvridhhi*, *Pleehavridhhi*, and *Jwara* were found in 32 (100%), 28 (87.5%), 28 (87.5%), 21 (65.62%), and 18 (56.25%) patients, respectively. Maximum 24 (75%) patients had *Akshikootashotha*, 14 (43.75%) had *Udarashoola*, 13 (40.63%) had *Pindikodweshntana* and 9 (28.13%) patients had *Sandhishoola*.

**Table 1: Ingredients of Triphaladi Avaleha**

Sanskrit name	Latin name	Part used	Quantity
<i>Amalaki</i>	<i>Emblca officinalis</i> Gaertn.	Pericarp	1 part
<i>Haritaki</i>	<i>Terminalia chebula</i> Retz.	Pericarp	1 part
<i>Vibhitaki</i>	<i>Terminalia bellerica</i> Roxb.	Pericarp	1 part
<i>Katuki</i>	<i>Picrorhiza kurroa</i> Royle. ex Benth.	Root	1 part
<i>Kakmachi</i>	<i>Solanum nigrum</i> Linn.	Whole plant	1 part
<i>Kutaja</i>	<i>Holarrhena antidysenterica</i> Wall.	Bark	1 part
<i>Haridra</i>	<i>Curcuma longa</i> Linn.	Rhizome	1 part
<i>Vidanga</i>	<i>Embelia robusta</i> Burm.	Fruit	1 part
<i>Guduchi</i>	<i>Tinospora cordifolia</i> Willd.	Stem	1 part
<i>Shweta</i>	<i>Trianthema</i>	Root	1 part
<i>Punarnava</i>	<i>portulacastrum</i> Linn.		
<i>Sharapunkha</i>	<i>Tephrosia purpurea</i> Linn.	Root	1 part
<i>Madhu</i>	-	-	q.s.
<i>Sharkara</i>	<i>Saccharum officinarum</i> Linn.	-	q.s.
<i>Chaturjata (Prakshepa)</i>			
<i>Twak</i>	<i>Cinnamomum zeylanicum</i> Blume	Bark	q.s.
<i>Ela</i>	<i>Elettaria cardamomum</i> Maton	Fruit	q.s.
<i>Tamalapatra</i>	<i>Cinnamomum tamala</i> Nees and Eberm	Leaf	q.s.
<i>Nagakeshara</i>	<i>Ochrocarpus longifolius</i> Benth. and Hook.	Stamens	q.s.

## Results

### Effect of therapies

The trial drug showed highly significant results ( $P < 0.001$ ) in the features of *Panduta*, *Daarbalya*, *Akshikootashotha*, and *Jwara*. *Triphaladi Avaleha* also gave significant results ( $P < 0.01$ ) in the features of *Udarashoola* and *Pleehavridhhi* and significant results ( $P < 0.05$ ) in *Yakritvridhhi*, *Pindikodweshntana*, and *Sandhishoola* [Table 2]. The results with the control drug were insignificant ( $P > 0.1$ ) in all the cardinal features except *Yakritvridhhi* which was significant ( $P < 0.05$ ) [Table 3].

In the patients treated with the trial drug, SGOT was decreased which was statistically significant ( $P < 0.01$ ) and SGPT was also decreased which was significant ( $P < 0.05$ ). The effect of the trial drug on all other parameters except SGOT and SGPT were found to be statistically insignificant ( $P > 0.1$ ) [Table 4], while the effect of the control drug on all the laboratory parameters was statistically insignificant ( $P > 0.1$ ) [Table 5].

*Triphaladi Avaleha* gave significant results ( $P < 0.01$ ) in relieving *Panduta* and *Sandhishoola* and significant results ( $P < 0.05$ ) in relieving *Akshikootashotha*, *Jwara*, and *Pindikodweshntana* in comparison to the control drug [Table 6].

The trial group reduced serum ferritin level to 3.75%, while it was found increased by 23.96% in control group [Table 7].

Post-treatment follow-up was done after 8 weeks of stopping the active treatment. Increase in BT, weight gain, height gain, splenomegaly, hepatomegaly, and clinical signs and symptoms were checked in the follow-up session. *Triphaladi Avaleha* increased

**Table 2: Effect of therapy on the signs and symptoms in Group A**

Signs and symptoms	n	Mean score			% Relief	SD	SE	t	P
		BT	AT	X					
Paandutaa	13	1.69	0.92	0.77	45.45	0.44	0.12	6.32	<0.001
Daurbalya	8	1.13	0.25	0.88	77.78	0.35	0.13	7.00	<0.001
Akshikootashotha	8	1.38	0.25	1.13	81.82	0.35	0.13	9.00	<0.001
Jwara	7	1.14	0.00	1.14	100.00	0.38	0.14	8.00	<0.001
Aruchi	3	1.33	0.00	1.33	100.00	0.58	0.33	4.00	>0.05
Udarashoola	6	1.33	0.00	1.33	100.00	0.52	0.21	6.32	<0.01
Pleehaavridhhi	10	1.80	1.10	0.70	38.89	0.67	0.21	3.28	<0.01
Yakritvridhhi	11	1.36	0.73	0.63	46.67	0.81	0.24	2.61	<0.05
Pindikodweshtana	4	1.75	0.00	1.75	100.00	0.96	0.48	3.66	<0.05
Sandhishoola	3	1.67	0.00	1.67	100.00	0.58	0.33	5.00	<0.05

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error

**Table 3: Effect of therapy on the signs and symptoms in Group B**

Signs and symptoms	n	Mean score			% Relief	SD	SE	t	P
		BT	AT	X					
Panduta	11	1.73	1.55	0.18	10.53	0.40	0.12	1.49	>0.1
Daurbalya	11	1.09	0.82	0.27	25.00	0.65	0.19	1.39	>0.1
Akshikootashotha	9	1.77	1.33	0.44	25.00	0.73	0.24	1.84	>0.1
Jwara	5	1.00	1.00	0.00	0.00	1.22	0.55	0.00	>0.1
Aruchi	8	0.88	0.38	0.50	57.14	0.76	0.27	1.87	>0.1
Udarashoola	5	0.80	0.40	0.40	50.00	0.89	2.24	1.00	>0.1
Pleehavridhhi	6	1.50	1.17	0.33	22.22	0.52	0.21	1.58	>0.1
Yakritvridhhi	9	1.78	1.11	0.67	37.5	0.71	0.24	2.83	<0.05
Pindikodweshtana	6	1.50	2.00	0.5	33.33	1.52	0.62	-0.81	>0.1
Sandhishoola	6	1.33	1.33	0.00	0.00	0.63	0.26	0.00	>0.1

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error

**Table 4: Effect of therapy on the laboratory parameters in Group A (n=13)**

Lab. parameters	Mean score			% Relief	SD	SE	t	P
	BT	AT	X					
Hb (gm %)	9.39	9.94	0.55	5.49	3.20	0.89	0.61	>0.1
TRBC/mm <sup>3</sup>	4.01	3.84	0.17	4.37	1.11	0.31	0.57	>0.1
PCV (%)	29.90	30.30	0.40	1.32	9.51	2.64	0.51	>0.1
Platelet count/mm <sup>3</sup>	214.31	321.15	106.84	49.86	171.17	47.47	2.25	>0.1
Total proteins (g)	7.18	7.23	0.05	0.75	0.51	0.14	0.38	>0.1
Albumin (g)	4.01	3.99	0.02	0.58	0.28	0.08	0.30	>0.1
Globulin (g)	3.17	3.25	0.08	2.43	0.52	0.14	0.53	>0.1
SGOT (IU/L)	73.54	52.46	21.08	28.66	24.04	6.67	3.16	<0.01
SGPT (IU/L)	73.77	48.46	25.31	34.31	33.75	9.36	2.70	<0.05
Alkaline phosphatase (IU/L)	126.08	140.77	14.69	11.65	34.22	9.49	1.55	>0.1
S. Bil. (mg/dl)	2.07	1.72	0.35	16.73	0.61	0.17	2.06	>0.05
S. Iron (µg/dl)	169.31	178.23	8.92	5.27	22.30	6.19	1.44	>0.1
S. TIBC (µg/dl)	228.00	214.15	13.85	6.47	39.35	10.91	1.27	>0.1
S. Ferritin (ng/ml)	4721.22	4544.26	176.96	3.75	4397.93	1219.77	0.15	>0.1

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error, PCV: Packed cell volume, SGOT: Serum glutamate oxaloacetate transaminase, SGPT: Serum glutamate pyruvate transaminase, TIBC: Total Iron binding capacity, TRBC: Total red blood corpuscles

the interval between BTs by 5 days in eight patients (61.53%) in the treated group. The control drug did not increase the interval between BTs in any patient in the control group. It was observed that 11 patients (84.62%) had a weight gain of 2 kg in the treated

group while 4 patients (36.36%) had a weight gain of 1 kg in the control group. Ten patients (76.92%) had a height gain of 2 cm in the treated group, while there was no height gain in any of the patients of the control group. In the treated group, there was no



**Table 5: Effect of therapy on the laboratory parameters in Group B (n=11)**

Lab. parameters	Mean score			%	SD	SE	t	P
	BT	AT	X	Relief				
Hb (gm %)	10.88	10.11	0.77	7.64	2.89	0.87	0.88	>0.1
TRBC/mm <sup>3</sup>	4.16	3.84	0.32	7.76	1.00	0.30	1.07	>0.1
PCV (%)	32.79	30.72	2.07	6.75	8.59	2.59	0.79	>0.1
Platelet count/mm <sup>3</sup>	239.36	303.82	64.45	26.93	108.70	32.78	1.97	>0.1
Total proteins (g)	7.23	7.08	0.15	2.01	0.52	0.16	0.93	>0.1
Albumin (g)	4.08	3.87	0.21	5.12	0.34	0.10	2.03	>0.05
Globulin (g)	3.15	3.21	0.06	2.02	0.59	0.18	0.36	>0.1
SGOT (IU/L)	73.64	68.00	5.64	7.65	49.41	14.89	0.38	>0.1
SGPT (IU/L)	83.64	78.28	5.37	6.41	55.69	16.79	0.32	>0.1
Alkaline phosphatase (IU/L)	122.27	134.73	12.45	10.19	49.46	14.91	0.84	>0.1
S. Bil. (mg/dl)	1.60	1.23	0.37	23.29	0.90	0.27	1.37	>0.1
S. Iron (µg/dl)	194.09	193.45	0.64	0.33	8.14	2.45	0.26	>0.1
S. TIBC (µg/dl)	174.45	174.45	0.00	0.00	5.06	1.53	0.00	>0.1
S. Ferritin (ng/ml)	3912.19	4849.68	937.49	23.96	2104.46	634.52	1.48	>0.1

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard Error, PCV: Packed cell volume, SGOT: Serum glutamate oxaloacetate transaminase, SGPT: Serum glutamate pyruvate transaminase, TIBC: Total Iron binding capacity, TRBC: Total red blood corpuscles

**Table 6: Comparative efficacy of Group A with Group B on the cardinal features**

Symptoms	% Relief		Mean	t value	P value
	Group A	Group B			
	Group difference				
<i>Panduta</i>	45.45	10.63	0.587	3.402	<0.01
<i>Daurbalya</i>	77.78	25.00	0.602	2.377	>0.05
<i>Akshikootashotha</i>	81.82	25.00	0.681	2.403	<0.05
<i>Jwara</i>	100.00	0.00	1.143	2.357	<0.05
<i>Aruchi</i>	100.00	57.14	0.833	1.709	>0.1
<i>Udarashoola</i>	100.00	50.00	0.933	2.172	>0.05
<i>Pleehavriiddhi</i>	38.89	22.22	0.367	1.14	>0.1
<i>Yakritvriiddhi</i>	46.67	37.50	0.031	0.088	>0.1
<i>Pindikodweshtana</i>	100.00	33.33	2.25	2.612	<0.05
<i>Sandhishoola</i>	100.00	0.00	1.667	3.819	<0.01

further splenomegaly or hepatomegaly in any patient, while six patients (54.55%) in the control group had further splenomegaly of 1 cm. No further increase in the severity of signs and symptoms was observed in the treated group. No adverse effects were reported by any of the patients.

### Overall effect of therapies

In trial group, five patients (38.46%) showed maximum improvement, five patients (38.46%) showed moderate improvement, two patients (15.38%) had mild improvement, while no improvement was seen in one patient (7.7%). In control group, two patients (18.18%) showed moderate improvement, four patients (36.36%) had mild improvement and five patients (45.46%) had no improvement [Table 8].

### Discussion

Hemoglobinopathies constitute a major public health problem internationally, particularly in the developing world as it has

**Table 7: Comparative efficacy of the trial drug with the standard control on the laboratory parameters (n=22)**

Lab. parameters	% Relief		Mean	t value	P value
	Group A	Group B			
	Group difference				
Hb (gm %)	5.49	7.64	1.3189	1.049	>0.1
TRBC/mm <sup>3</sup>	4.37	7.76	0.147	0.339	>0.1
PCV (%)	1.32	6.75	2.473	0.663	>0.1
Platelet count/mm <sup>3</sup>	49.86	26.93	42.392	0.708	>0.1
Total proteins (g)	0.75	2.01	0.199	0.944	>0.1
Albumin (g)	0.58	5.12	0.186	1.472	>0.1
Globulin (g)	2.43	2.02	0.013	0.0586	>0.1
SGOT (IU/L)	28.66	7.65	15.441	0.998	>0.1
SGPT (IU/L)	34.31	6.41	19.944	1.08	>0.1
Alkaline phosphatase (IU/L)	11.65	10.19	2.238	0.131	>0.1
S. Bil. (mg/dl)	16.73	23.29	0.027	0.0857	>0.1
S. Iron (µg/dl)	5.27	0.33	9.559	1.344	>0.1
S. TIBC (µg/dl)	6.47	0.00	13.846	1.155	>0.1
S. Ferritin (ng/ml)	3.75	23.96	1114.455	0.767	>0.1

PCV: Packed cell volume, SGOT: Serum glutamate oxaloacetate transaminase, SGPT: Serum glutamate pyruvate transaminase, TIBC: Total Iron binding capacity, TRBC: Total red blood corpuscles

**Table 8: Clinical assessment of the results in 24 patients**

Assessment of result	Group A		Group B	
	No. of patients	%	No. of patients	%
Maximum improvement	5	38.46	0	0.00
Moderate improvement	5	38.46	2	18.18
Mild improvement	2	15.38	4	36.36
No improvement	1	7.7	5	45.46

the least resources for coping with the problem. Thalassemia is one such disease which affects a large number of individuals worldwide. It is an inherited single-gene autosomal recessive disorder of the RBCs, resulting from absence or deficiency or one or more of the constituents of hemoglobin. It usually results in underproduction of normal globin proteins, often through mutations of regulatory genes. Reduced synthesis of one of the globin chains results in the formation of abnormal hemoglobin molecules, which, in turn, causes anemia, the characteristic presenting symptom of the thalassemias.

The ingredients of *Triphaladi Avaleha* are *Haritaki*, *Amalaki*, *Vibhitaki*, *Katuki*, *Kakamachi*, *Kutaja*, *Haridra*, *Vidanga*, *Guduchi*, *Shweta Punarnava*, *Sharapunkha*, *Sharkara*, *Madhu*, and *Prakshepa of Chaturjata*. Most of the drugs have properties like *Aamaapaachana*, *Deepana*, *Rochana*, and *Srotoshodhana* which correct the *Agni* and help to alleviate *Agnimandya* and *Aruchi*. Thus, they improve appetite and digestion, as well as remove obstruction in the channels, so that the transformation of *Dhatu*s becomes undisturbed and, thus, it relieves *Daurbalya*. *Anulomana Guna* helps in the correction of digestive process. In this way, *Aruchi*, *Udarashoola*, *Pindikodweshtana*, and *Sandhishoola* are relieved. *Jwaraghna Guna* of *Triphala*, *Katuki*, *Guduchi*, and *Sharapunkha* alleviates *Jwara*. The drugs like *Triphala*, *Katuki*,<sup>[13]</sup> *Kakamachi*,<sup>[14]</sup> *Haridra*,<sup>[15,16]</sup> *Guduchi*,<sup>[17]</sup> *Shweta Punarnava*, and *Sharapunkha*<sup>[18]</sup> act in the *Moola Sthanas* of *Rasavaha* and *Raktavaha Srotas*. They have *Pandughna*, *Bhedana*, *Pittasarakha*, *Yakrit-Pleehavridhahara*, *Raktashodhana*, *Raktasthapana*, and *Shonitaprasadana* properties which relieve *Panduta*, *Akshikootashotha*, *Yakritvridhhi*, and *Pleehavridhhi*. They are also hepatoprotective, which may help to decrease SGPT, SGOT, alkaline phosphatase, and s. bil. Drugs were selected from *Lohashodhana* and *Lohamarana Gana*, which may decrease serum iron and serum ferritin levels. *Rasayana* and *Vayasthapana*, as well as antioxidant and immunomodulatory activities enhance *Bala* and *Vyadhikshamatva*.

In short, *Aamaapachana*, *Deepana*, *Rochana*, *Jwaraghna*, *Vishaghna*, *Balavarnakara*, *Brimhana*, *Rasayana*, and *Tridosahara* properties do *Vatapittashamana* and relieve the signs and symptoms of thalassemia. Iron chelation may be done through *Lohashodhana*, *Lohamarana*, *Lekhana*, and *Bhedana Karmas*. Also, *Raktashodhana*, *Raktaprasadana*, *Shonitasthapana*, and *Varnya* properties decrease the rapid destruction of RBCs, thus prolonging their life span, which increases the interval of BT. All these factors improve the quality of life of thalassemic patients.

Serum ferritin level is the hematological criterion for assessing iron overload in thalassemic patients. Decreased serum ferritin indicates decreased iron overload in the patients. Though the comparative data are statistically not significant, the trial group decreased serum ferritin level by 3.75%, while in control group, serum ferritin level was increased by 23.96%. This showed that trial drug had good result to decrease the iron overload in thalassemic patients in comparison to control drug. The level of serum iron was increased. No particular reason was found for the decrease in serum ferritin and increase in serum iron levels. Further extensive studies are needed to evaluate these findings.

## Conclusion

There is no exact correlation for thalassemia in Ayurveda. *Beejabhagavayavadushti* is found to be the chief factor in this disease. Prevention can be achieved through *Atulyagotriya Vivaha* as well as modern diagnostic techniques. *Triphaladi Avaleha* has various properties which help to relieve the signs and symptoms of the disease, as well as decrease the iron overload. So, it can be given as an adjuvant therapy with modern medical management.

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## हिन्दी सारांश

# बीजदुष्टिजन्यपाण्डु(थेलेसीमिया) में त्रिफलादि अवलेह का चिकित्सकीय अध्ययन

अभिषेक वाय. पाटलिया, विरेन्द्रकुमार कोरी, कल्पना एस. पटेल, राजगोपाल एस.

बीजदुष्टिजन्यपाण्डु अंतरराष्ट्रीय स्तर पर विशेषकर विकासशील देशों में एक बड़ी समस्या है, इस समस्या को दूर करने के बहुत कम स्रोत पाये जाते हैं। थेलेसीमिया लाल रक्त कोशिकाओं की विकृति है। हर पंद्रह दिन में रक्तदान, बारबार व्याधि संक्रमण, लौह की अधिकता और न्यूनतम शैक्षणिक प्रवृत्ति की वजह से जीवन दुःखद बन जाता है। हर वर्ष थेलेसीमिया की चिकित्सा में प्रायः १००० करोड रुपये खर्च होते हैं। इस प्रकार की जटिल व्याधियों को दूर कर पाना इतना आसान नहीं है। प्रस्तुत अध्ययन थेलेसीमिया में त्रिफलादि अवलेह के प्रभाव के मूल्यांकन से संबंधित है। अध्ययन में १ से १५ वर्ष की वय के ३२ रुग्णों को पंजीकृत कर चिकित्सकीय वर्ग(वर्ग अ) तथा आदर्श नियन्त्रित वर्ग(वर्ग ब) इस प्रकार दो वर्गों में विभाजित किया गया। वर्ग अ में त्रिफलादि अवलेह को गोदुग्ध के अनुपान से तथा वर्ग ब में डिफेरीप्रोन दिया गया। १२ सप्ताह की चिकित्सा तथा दो मास के अनन्तर-पुनःपरीक्षण के पश्चात् लक्षणात्मक और प्रयोगात्मक मानको का मूल्यांकन किया गया। दोनो वर्गों में पाण्डु और संधिशूल को मिटाने में सांख्यकीय दृष्टि से अतिसार्थक तथा ज्वर, अक्षिकूटशोथ और पिण्डिकोद्वेष्टन में सांख्यकीय दृष्टि से सार्थक परिणाम प्राप्त हुए। चिकित्सकीय वर्ग में ३८.४६ प्रतिशत रुग्णों को ज्यादा लाभ, ३८.४६ प्रतिशत रुग्णों को मध्यम लाभ और १५.३८ प्रतिशत रुग्णों को अल्प लाभ मिला, जबकि ७.७ प्रतिशत रुग्णों को कोई लाभ नहीं मिला।