Clinical Researches

Evaluation of *Dhatri Avaleha* as adjuvant therapy in Thalassemia (*Anukta Vyadhi* in *Ayurveda*)

Ruchi Singh*, K. S. Patel, I. P. Anand*****

Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar

Abstract

Thalassemia is the commonest single gene disorder in India. About 10,000 infants with Thalassemia major are born every year. The present study was under taken with a hope to prevail better quality of life to the Thalassemic patients. Pallor being the chief complaint, a randomized controlled trial was undertaken with *Dhatri Avaleha* as it is specially mentioned for *Pandu*, *Kamala* & *Haleemaka Roga*. Children between age group of 1 to 15 years were randomly divided in two groups: Drug treated group (Group A) and Control group (Group B). Assessment was done on subjective and objective parameters after 30 and 60 days of treatment with follow up of two month. Statistically significant ($P<0.01$) result was obtained in Blood transfusion interval in group 'A' in comparison to group 'B'. *Dhatri Avaleha* may have a potential to increase blood transfusion interval and decrease secondary infection and thus it can be used as supportive therapy with modern medical management.

Key words: Thalassemia, Pandu, *Kamala, Haleemaka, Dhatri Avaleha*

Introduction

Today is the era of advancement, which can be seen in each field either it might be media, electronic, science or in the day-to-day life i.e. dietetic habits, daily routines as well, hence the ultimate effect of all these changes go towards the problems in coming generation[1]. These changes occur in the field of medical science too, among them Thalassemia is a new disease for *Ayurveda* and thus called as "*Anukta Vyadhi*".

Thalassemia is an inherited blood disorder in which body is unable to make adequate hemoglobin, which is present in the red cells. Normally red cells survive for 120 days but in Thalassemia red cell survival is reduced. In India the combined carrier rate of b Thalassemia, HbE & Sickle Cell Anemia is 3.9%. i.e. 3 crore Indians are Thalassemic carriers and 8000 to 10,000 Thalassemia major are born every year in India. The prevalence for b Thalassemia carrier state varies 0-17% in different ethnic groups. It is very high among certain communities like Punjabis, Sindhis, Gujaratis (Lohana and Bhanushali), Bengalis, Parsis. Thus the morbidity and mortality of this disease has aroused a lot's of research for its alleviation and cure. So keeping all these views in mind great hopes are being laid on *Ayurveda* as cost effective adjuvant therapy in Thalassemia2 to prevent its complication and hazardous effects.

The present study is an attempt to analyze the efficacy of *Dhatri Avaleha*[3] in management of Thalassemia in comparison to a control group managed by routine modern therapy. The drug had been chosen keeping in view its *Rasayana*, *Antioxidant* and *Hepatoprotective* properties.

The main aim of study was to provide a better quality of life and to reduce complication and delay the blood transfusion interval by *Ayurvedic* medicines.

Material and Methods

Selection of patients: Patients attending the I.P.D. of Thalassemia ward of M. P. Shah Medical College and O.P.D. of *Kaumarabhritya* Department, I.P.G.T & R.A. Hospital, Jamnagar fulfilling the criteria of selection were incorporated in the study irrespective of age, sex, caste etc.

Criteria for selection of patients: On the basis of clinical sign and symptoms, pathological investigations.

*Lecturer, Kaumarabhritya, SRM State Ayurvedic College, Bareilly (U.P.)
Email: drruchi6@gmail.com
**Head of the Dept. of Kaumarabhritya, I.P.G.T. & R.A.
***M. D. (Ped.), Hon. Pediatrician, Jamnagar.

DOI: 10.4103/0974-8520.68199

1. Patients having Hb <10 gm% were selected.
2. With the clinical manifestation of disease in the age group 1-15 years.

Sampling method: **Random sampling**

Criteria for exclusion of patients:

1. Complicated cases of Thalassemia (like HIV, Hepatitis B or other viral diseases etc.).
2. Patients having Blood Transfusion interval < 15 days.

Assessment criteria

A detailed proforma was prepared which has clinical parameters (subjective and objective) with the score. The score can be counted before and after 30 days, 60 days of treatment. The parameters were as follows:

Subjective parameters

Balakshaya (Fatigue), *Sandhi Shoola* (Joint pain), *Udar Shoola* (Abdominal pain), *Shramaja Shwasa* (Dyspnoea), *Avasada* (Depression), *Panduta* (Pallor), *Pleehavriddhi* (Spleenomegaly), *Yakritvriddhi* (Hepatomegaly), Irritable bowel syndrome, Blood transfusion interval duration.

Objective parameters

Routine hematological investigation (Hb%, TLC, DLC, ESR, PCV, MCV, MCH, MCHC, and Routine biochemical investigations (S. Alb, S.Glob, SGOT, SGPT, S. Alk. Phosphatase, S. Bil.).

- A special proforma was made to study the etiopathogenesis as well as response to the given treatment and any complication.

Description of grades and its relation with severity:

For the purpose of statistical assessment of results, we have used some grades, grade point considering the severity of different sign and symptoms and laboratory findings as follows:

Severity	Grade	Grade Point
Severe	G3	3
Moderate	G2	2
Mild	G1	1
Normal	G0	0

Assessment of result

Maximum Improvement: Above 75% relief in clinical sign and symptoms along with blood transfusion interval increases more than 10 days.

Moderate Improvement: Above 50% to 75% relief in clinical sign and symptoms along with blood transfusion interval increases more than 5 to 10 days.

Mild Improvement: Above 25% to 50% relief in clinical sign and symptoms along with blood transfusion interval increases up to 5 days.

No Improvement: Equal or Less than 25% relief in clinical sign and symptoms and blood transfusion interval have no change.

Statistical analysis

Student 't' test (paired and unpaired) was used for assessing the result of clinical study.

Duration of trial: Treatment Period - 60 days [02 months].

Follow up: 02 months.

Procedure of drug administration:

Trial drug: These drugs consist of the following ingredients in equal ratio as stated by Acharya *Charaka* in *Pandu Roga* Chikitsadhikara[3].

This Avaleha form of drug was prepared according to classical method and administered in scheduled dose according to age group-

- 1 to 5 yrs.: 1-3 gms
- >5 to 10 yrs.: 4-6 gms
- >10 to 15 yrs.: 7-9 gms
- *Anupana* - Milk

} Twice daily

Observations and Results

Total 19 patients were enrolled with 11 patients in Group 'A' & 8 patients in Group 'B'. In the Group 'A' 8 patients completed the course of treatment with follow up and in Group 'B'6 patients were continued under observation. Among 19 patients 09 (47.37%) belonged to an age group of 1 to 5 years. It may be due to that most of the Thalassemic patients (Thalassemia major) are diagnosed within the age group of 1 year4. Male

Drugs Name	Family	Latin Name	Part used	Proportion
Amalaki	Euphorbiaceae	*Embellica officinalis*	Fresh fruit	Q.S.
Yastimadhu	Leguminoceae	*Glycyrrhiza glabra*	Root	1 part
Pippali	Piperaceae	*Piper longum*	Dried fruit	1/4th part
Shunthi	Zingiberaceae	*Gingiber officinale*	Dried rhizome	1 part
Draksha	Vitaceae	*Vitis vinifera*	Ripe fruit	1/4th part
Vanshalochana	Graminae	*Bambusa arundinacea*	Extract	1 part
Sharkara	Graminae	*Saccharum officinarum*	Crystals	1/4th part
Madhu	-	Honey	Nectar	Prakshep dravya

and female ratio was found almost equal. Maximum number i.e. 14(73.68%) were Hindu, it might be due to dominancy of Hindu in Jamnagar district. The incidence of Thalassemia was maximum i.e. 03 (15.79%) present in Lohana and Kumahar community in comparison to others. Because it is more common in these Gujarati community (Lohana, bhanushali and katchi et.)5. Majority of the patients i.e. 12 (63.61%) were diagnosed within the age of 1 yr6. It may be due to clinical manifestation of Thalassemia major starts within the age of first year of life. Before starting the trial drug no. of blood transfusion was found > 100 times in 04 (21.05%) patients. It might be due to rapid breakdown of RBCs leading to severe anemia which can only be compensated by blood transfusion. It was observed that maximum i.e. 16 (84.21%) patients were having Thalassemia major because of ß Thalassemia major prevalent in Gujarat and as well in India. Most of the patients i.e. 13 (68.42%) found not taking any iron chelators. The reason behind not taking iron chelators because of these drugs are very costly and most of the patients were belonging to lower socio-economic group. During surgical history majority i.e. 17 (89.47%) patients having splenectomy not done; it might be due to most of the patient registered from G. G. Singh, hospital were under regular blood transfusion. Only 06 (31.58%) patients were having consanguieous marriage history in parents. It may be due to that most of the patients were from Hindu religion.

Most of the patients i.e.08 (42.11%) were having hepato - spleenomegaly, which may be due to regular blood transfusion. Only 07 patients, parents were investigated for NESTROFT. It shows unawareness and educational status of the parents. *Amla* and *Katu Rasa* predominance were observed in 13 (68.42%) patients, while *Guru* and *Snigdha Guna* predominance found in 17(89.47%) and 11(57.89%) patients respectively. During study *Vata-Pitta Prakriti* was found predominant in 16 (84.21%) patients it might be due to Rakta dushti.

Among chief complaints, pallor was found in 100% patients, while 89.47% patients showed the symptoms of fatigue, joint pain, abdominal pain, dyspnoea was found in 68.42% patients. The 52.63% patients having arrhythmia, 47.37% patients had spleen enlargement, 42.11% patients had symptoms of Irritable bowel syndrome. Chest pain and Depression was found only in 05.26% patients.

In this present clinical study, maximum i.e. 55.99% patients having *Dushti* of *Raktavaha Srotas*, 43.15% patients had *Rasavaha Srotodushti*, while 30.05% patients had *Dushti* of *Medavaha Srotas*. The 23.53% and 23.94% patients had *Mamsavaha* and *Majjavaha Srotodushti* respectively. *Asthivahasrotodushti* was found only in 24.18% patients.

After the completion of treatment with follow up result obtained in 08 patients of Group A *(Dhatri Avaleha)* i.e highly significant ($p<0.001$) in fatigue, significant ($p<0.01$) in abdominal pain and pallor, while insignificant ($p>0.10$) in joint pain, depression spleenomegaly, and irritable bowel syndrome.

The result obtained in 06 patients of Group B (Control group) in which patient were under observation showed insignificant result in all the symptoms with the negative percentage values.

In associated complaints of Group 'A' (Treated group) this therapy provided highly significant ($p<0.001$) result in *Aruchi* with the percentage of 92.86%, significant ($p<0.05$ &0.01) result in *Alasya*, *Mandagni*, *RURTI* and T*rishna* with the percentage of 100%, 81.82%, 75%, 44.45% relief respectively, while insignificant ($p>0.10$) result obtained in *Angamarda* with 25% relief only.

In Group B (Control Group), statistically insignificant result was observed with the 11.43% relief in *Aruchi*, 25% in *Angamarda*, 12.50% in *Mandagni*, no relief in *Aalasya* and Recurrent respiratory infection and -20% in *Trishna*.

In blood transfusion interval duration statistically significant ($p<0.01$) result found during first interval duration in Group A (Trial Group) comparative to Group B (Control Group). In objective parameters both the group showed insignificant results.

Table 1: Improvement in chief complaints after treatment

Sr. No.	Chief complaints	After 30 days		After 60 days	
		Group A (%)	Group B (%)	Group A (%)	Group B (%)
1	Fatigue	23.53	8.33	70.59	-8.33
2	Joint pain	28.57	14.28	100	-14.28
3	Abdominal pain	28.57	12.50	78.57	25
4	Dyspnoea	42.86	12.50	77.78	-12.50
5	Depression	14.29	20.00	62.05	20.00
6	Pallor	18.75	7.14	37.5	-7.14
7	Spleenomegaly	10.00	-12.50	30.00	-12.50
8	Irritable bowel syndrome	62.50	50.00	100	33.33

Table 2: Improvement in associated complaints after treatment

Sr. No.	Associated complaints	After 60 days	
		Group A (%)	Group B (%)
1	Aruchi	92.86	11.43
2	Angamarda	100	25.00
3	Alasya	100	0.00
4	Mandagni	81.82	12.50
5	RURTI (recurrent upper respiratory tract infection)	75.00	0.00
6	Trishna	45.45	-20

Table 3: Effect of therapy in blood ransfusion interval duration

Symptom	Treatment Group	Blood transfusion interval	Mean ± S.D.	df (n-1)	't' Value	'*P*' Value	Remarks
Blood Transfusion	Group-A	BT	21.43 ± 5.56				
		BTI-1	4 ± 2.2	6	4.0	<0.01	*Significant
		BTI-2	1.57 ± 6.63	6	0.63	>0.1	Insignificant
		BTI-3	2.25 ± 6.51	3	0.69	>.0.1	Insignificant
		BTI-4	1.67 ± 1.85	2	1.56	>.0.1	Insignificant
	Group -B	BT	18.5 ± 6.12				
		BTI-1	3 ± 4.34	5	1.69	>.0.1	Insignificant
		BTI-2	0 ± 2.1	5	-	-	-
		BTI-3	0 ± 2.53	4	-	-	-
		BTI-4	-1 ± 1.97	3	-1	>.0.1	Insignificant

Table 4: Result of clinical assesment in 14 patients

Assessment of Result	Group-A (n=8)				Group-B (n=6)			
	AT1		AT2		AT1		AT2	
	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%
Maximum improvement	0	0	2	25	0	0	0	0
Moderate improvement	0	0	5	62.5	0	0	0	0
Mild improvement	3	37.5	1	12.5	1	16.66	0	0
No change	5	62.5	0	0	5	83.33	6	100

AT-1: After treatment of 30 days [01 month]; AT-2: After treatment of 60 days [02 months]

Discussion

Intake of tea in small children fascinated, which is generally supported by doctors mostly due to its iron chelating property. Predominance of anger and irritation due to prolong ill health, different types of restriction, isolation and vitiation of *Pitta Dosha*.

On the basis of special proforma *Vata-Pitta* predominance was observed along with *Rakta Dushti*. The symptoms described in *Haleemaka Vyadhi* in *Charaka Samhita Chikitsa* (16/132,133) seem to be very nearer to Thalassemia as follows: *Haritashyavapeetakaha*, this *varna* seems to be yellowish brown colour in thalassemia due to excess iron deposition beneath the skin. Other features like *Balautsaha kshaya*, *Tandra*, *Mandagni*, *Mridujwara*, *Angamarda*, *Shwasa*, *Trishna* and *Aruchi*, are clinically found predominant in Thalassemic patients.

As pallor or *Raktalpata* is the main cardinal feature of the disease for which patients seeks medical help. Thus the name of the disease can be given as: *Kulaja Pandu (Raktalpata)* in *Bala* / *Anuvanshika Pandu (Raktalpata)* in *Bala* / *Anuvanshika Tridoshaja Pandu (Raktalpata)* in *Bala* / *Beeja Dushti Janya Pandu (Raktalpata)* in *Bala*. But after detailed literary and clinical research conclusion can be drawn that Thalassemia may be simulated with the disease *Haleemaka*. *Ayurvedic* formulations along with supportive modern therapy may provide better quality of life to the diseased.

Conclusion

Dhatri Avaleha may have a potential to reduce blood transfusion interval duration along with other secondary infection. It can be given as supportive therapy with modern medical management.

References

1. Taneja Anubha, Expectations and obligations of Thalassemic, 5th national Thalassemia conference 11th, 12th November 2006 (119-120), MAMC Auditorium, New Delhi.
2. Varma I.C., Puri R., Thakur S., Saxena R., Strategies for control of ß-thalassemia in India, 5th national Thalassemia conference 11th, 12th November 2006 (76-82), MAMC Auditorium, New Delhi.
3. Charaka Samhita with 'Vidyotini Hindi Commentary by Pt. Kashinath Shastry and Dr. Gorakhnath Chaturvedi, Part I and 2, Chaukhamba Bhauati Academy, Varanasi, 1998.
4. I.A.P. Text book of Pediatrics Edi. A Parathasarathy, Jaypee Brothers New Delhi, Ist Edition, 2000.
5. Deeka Deepika, Public Awareness and Prevention of Thalassemia Major, National Thalassemia Bulletin, Vol. 11 No, 2 May 2005.
6. Rudolf's Pediatrics Edi. Abraham M. Rudolf PH., Prentice Hall International INC, XXth Edition, 1996.
7. Agrawal M.B., Rathi A. Shyam, Gene therapy in thalassemia, 5th national Thalassemia conference 11th, 12th November 2006 (94-103), MAMC Auditorium, New Delhi.
8. Solkar M.H., Mamta Manglani, Psychosocial evaluation in Thalassemic children; 1st international Symposium on Thalassemia, 8th - 9th Octobar, 2005 (44) Pune.
9. Agrawal M.B, Total managment of Thalassemia: advances, 1st international Symposium on Thalassemia, 8th -9th Octobar, 2005 (38) Pune.
10. Agrawal M.B, Agrawal U.M., Rajadhyaksha, Munot Sameer, Assesment of cardiac iron overload: Role of MRI; 1st international Symposium on Thalassemia, 8th -9th Octobar, 2005 (36) Pune.

हिन्दी सारांश

थेलेसेमिया रोग में धात्री अवलेह के चिकित्सीय प्रभाव का अध्ययन

रुचि सिंह, के. एस. पटेल एवं आई. पी. आनंद

थेलेसेमिया भारत में सामान्यतयाः एक रंग सूत्रात्मक विकृति मिलती है। प्रतिवर्ष लगभग १०,००० थेलेसेमिया मेजर से पीड़ित बच्चे जन्म लेते हैं। थेलेसेमिया व्याधि की चिकित्सा आयुर्वेदिक औषधों से अनुसन्धान के रूप में एक आशा के साथ की गई ताकि बच्चों को अच्छा सा जीवन प्रदान हो। इस व्याधि में मुख्य लक्षण पांडुता है। अतः चिकित्सीय अध्ययन के लिये धात्री अवलेह का चयन किया। जो विशेषतः चरक चिकित्सास्थान २६ में पाण्डु, कामला और हलीमक व्याधि की चिकित्सा में बताया गया है। एम. पी. शाह मेडिकल कॉलेज, जामनगर थेलेसेमिया वॉर्ड और कौमारभृत्य के ओ.पी.डी. से १ से १५ साल के बच्चों को इस अध्ययन के लिये लिया गया। समूह 'ए' आयुर्वेदिक औषधि और समूह 'बी' आधुनिक औषधि, इन दो समूहों में बाँट कर धात्री अवलेह को मूल्यांकन के लिये ६० दिन तक दिया गया और उसका मूल्यांकन ३० दिन तथा ६० दिन के बाद लक्षणात्मक और प्रयोगात्मक निश्चय रिसर्च प्रोफोर्मा की सहायता से किया गया। चिकित्सा पश्चात् भी दो मास तक अध्ययन किया गया। समूह 'ए' में समूह 'बी' की तुलना में ब्लड ट्रान्सफ्युझन की अंतराल अवधि में सांख्यकीय द्दष्टि से महत्त्वपूर्ण ($p<0.01$) वृद्धि पायी गयी। निष्कर्ष : धात्री अवलेह में दो ब्लड ट्रान्सफ्युझन के बीच की अवधि बढ़ाने और द्वितीयक संक्रमण कम करने की क्षमता है। धात्री अवलेह थेलेसेमिया के रुग्णों में सहायक औषधि के रूप में आधुनिक चिकित्सा के साथ दी जा सकती है।