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 undertaken 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 generation¹. 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 some 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 Avaleha³ 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.
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**

Balaks (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.

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**

**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 year. Male
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.)15. 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 ε 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 consanguineous 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 hepatosplenomegaly, 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 52.65% patients having arrhythmia, 47.37% patients had splenomegaly, 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 Rakta vaha Srotas, 43.15% patients had Rasavaha Srotodushiti, while 30.05% patients had Dushti of Medavaha Srotas. The 23.53% and 23.94% patients had Mamsavaha and Majavaha Srotodushiti 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 Trishna 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 Alasya 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.

| 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 |
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: Haritashyavapetakaha, 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 Dushhti 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.

### 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       | RURT (recurrent upper respiratory tract infection) | 75.00 | 0.00 |
| 6       | Trishna                       | 45.45        | -20          |

### Table 3: Effect of therapy in blood transfusion 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 |
|                          | 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 assessment 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          |

AT1: After treatment of 30 days [01 month]; AT2: 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: Haritashyavapetakaha, 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.

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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.

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