ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Research Article

# CLINICAL EVALUATION OF T-AYU-HM PREMIUM IN SICKLE CELL ANEMIA PATIENTS: A RETROSPECTIVE STUDY

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**Article info**

**Article History:**
Received: 23-08-2022
Revised: 11-09-2022
Accepted: 23-09-2022

**KEYWORDS:**
Sickle cell anemia, sickle cell trait, T-AYU-HM Premium, Retrospective study.

## ABSTRACT

**Background:** The orphan status of sickle cell invites many researchers toward drug development in the past decade. A substantial number of clinical trials either understudies or in the planning stage focused on sickle cell disease. Sickle cell traits are often considered asymptomatic and the silent condition is associated with diverse complications.

**Objective:** To clinically evaluate the safety and effectiveness of T-AYU-HM Premium Tablets (300mg) in sickle cell anemia patients: an observational retrospective study

**Methodology:** This is a single-arm case-control retrospective study of sickle cell trait patients admitted to Dhanvantari Clinic from 2018 to 2020. Patients' vital and clinical information based on inclusion and exclusion criteria were collected and analyzed using SPSS software.

**Result:** A total of 100 patients with sickle cell traits were included in the study. The treatment exhibited significant improvement was seen in ($P<0.05$) in hemoglobin and red blood corpuscles. There wasn't any untoward response either from the patient or from laboratory parameters reported indicating no adverse effects were seen. There was an absolute improvement in overall health as a reduction of no of time hospitalization (0) and blood transfusion (0) in sickle cell trait patients. There was a significant improvement in minor and major clinical parameters of sickle cell trait patients.

**Conclusion:** The effect of T-AYU-HM Premium treatment in sickle cell trait patients suggests it is safe and effective. There was no adverse effect observed in the observational study. During entire study period, no single blood transfusion or hospitalization required. The significant improvement in the rate and frequency of painful crises indicates an improvement in pain-related quality of life in patients. This treatment of T-AYU-HM Premium was safe, cost-effective, and exhibit therapeutic potential in the management of sickle cell trait patients.

## INTRODUCTION

Sickle cell anemia is a hemoglobin disorder where even the government of India organized special provisions and support in the ministry of tribal affairs.[1] As we all know with improving technology and globalization the incidence of this hemoglobin disorder is also predicted to increase only.[2]

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Despite the fact about epidemiology and recent advances in the treatment of sickle cell anemia in past years it is still a global challenge for all.[3] The advancement in technology and tourism and considering ease of migration of the population across the countries might increase the possibility of hemoglobin disorder considered to increase in the future and presents a global challenge.[4] In India, sickle cell anemia mostly impacts the tribal population and therefore language barriers, information resources, and healthcare access are the major key factor for mapping the disease and providing healthcare facilities to them. A lot of efforts have been initiated to spread awareness on prenatal and premarital screening going to make a difference. The improvement in perception and approach towards the

sickle cell in tribal with constant such kind of program will change for sure.[5, 6] It has been already mentioned in previous studies that almost all of the affected babies of sickle cell anemia in medium- to well-resourced countries may now expect to live to adulthood but overall survival still lags.[7] The orphan status of sickle cell invites many researchers toward drug development in the past decade. A substantial number of clinical trials either understudies or in the planning stage focused on sickle cell disease. Sickle cell traits are often considered asymptomatic and the silent condition is associated with diverse complications. Sickle cell traits are mostly considered benign and therefore never emphasized more in its treatment or management. Because triggers which cause sickling for sickle cell disease can also cause sickling for sickle cell trait. Lack of attention, ignorance towards mild to moderate complications can induce further complications in patients. Therefore, adequate hygiene, hydration and awareness are important simultaneously better and treatment affordable options should also be emphasized for better quality of life in sickle cell traits.

T-AYU-HM Premium is a herbo-mineral formulation that possesses documented in-vitro anti-sickling activity. T-AYU-HM Premium has the potential to function as an anti-sickling traditional ayurvedic medicine mentioned in Table 1.

**Table 1: T-AYU-HM Premium Formulation Detail**

| Ingredient Name | Botanical Name | Part Used | Quantity |
|---|---|---|---|
| *Abraka Bhasma* | Calyx of Mica | - | 25 mg |
| *Loha Bhasma* | Calyx of iron | - | 12.5 mg |
| *Haritaki* | *Terminalia chebula* | Fruit | 25 mg |
| *Sunthi* | *Zingiber officinale* | Rhizome | 25 mg |
| *Shatavari* | *Asparagus racemosus* | Root | 25 mg |
| *Dadima* | *Punica granatum* | Fruit | 12.5 mg |
| *Jaiphal* | *Myristica fragrans* | Seed | 25 mg |
| *Pippali* | *Piper longum* | Fruit | 37.5 mg |
| *Guduchi* | *Tinospora cordifolia* | Stem | 37.5 mg |
| *Jivanti* | *Leptadinia reticlata* | Root | 37.5 mg |
| Storage condition: Store in dry and cool place. Keep away from direct sunlight. Do not refrigerate | | | |

The formulation manufactured by ATBU Harita Pharmaceutical Pvt Ltd. The formulations prepared in 300 mg tablet dosage form. *Terminalia chebula* and *Punica granatum* are just a few of the essential plants included in formulation. The formula has proven anti-sickling properties. [8,9] The anti-sickling action in the T-AYU-HM Premium formulation indicates that it has the potential to prevent the deregulation of Gardos channels. Ingredients in the formulations include medicinal extracts from *Punica Grantum* and *Tinospora Cordifolia* that have a metal chelating effect and act as strong antioxidants for the red blood cells. Ascorbic acid enhanced the likelihood of iron absorption, and the components are also a source of iron. Therefore, the formulation may have the potential to enhance the quality of life for sickle cell anemia patients.[10-15] The formulation T-AYU-HM Premium has already undergone in vitro testing, preclinical safety investigations, immunomodulatory activity research, clinical trial completion in Covid-19, and reported case studies of its therapeutic efficacy.

The present study was performed to clinically evaluate the effectiveness of T-AYU-HM Premium 300mg tablets in sickle cell anemia patients. The main aim of this study is to clinically evaluate T-AYU-HM Premium in sickle cell traits patients. The primary objectives were to evaluate the effect of treatment on complete blood counts and the effect of treatment on patients' symptoms. Whereas, the secondary objectives are to evaluate the following parameters: The effect of treatment on the Number of times the patient was hospitalized during the study period, the effect of treatment on the Number of pain crisis episodes during the treatment period, and the effect of treatment on number of times blood transfusions are required during the observation period.

**Methodology:** This observational case control single-arm study collected clinical data on sickle cell anemia (sickle cell trait) patients who received treatment from 1st January 2018 to 31st december,2020 from Dhanvantari Clinic, Ayurveda Healthcare and Research Centre, Vyara, Gujarat-India. The trialwas as per the following protocol the guideline, the declaration of Helsinki, standards of ICH-GCP, and local regulatory guidelines. The study was approved by Ethics Committee and registered prospectively with CTRI and registration number - CTRI/2022/02/040601. Prior informed consent has been excluded from the

participants considering the type and design of the study. The sample size was kept at 100 sample size. Total 120 days follow-up period is considered appropriate to observe the treatment outcome in patients.

**Inclusion criteria**

- Patients were treated with T-AYU-HM Premium for sickle cell anemia at Dhanvantari Clinic between 1st January 2018 to 31st December 2020.
- Patients with a diagnosis of sickle cell anemia (SCT/ SCD specification testing)
- Patients above years from both sexes from sickle hemoglobin.
- Patient's ≥ 3 months of follow-up data available from the first treatment at the centre.
- Patients visited the OPD of clinic regularly on the scheduled appointment date
- Patients who were hospitalized for crisis conditions.

**Exclusion Criteria**

- Patients who were taking other medicines for anemia
- Pregnant and lactating women.
- The patient's laboratory parameters data are not available.
- The patient follow-up is irregular

All patients were followed from the date of diagnosis to the date of their last scheduled visit or up to December 30, 2020. The date of the last scheduled visit was determined from a case report file maintained by the Dhanvanatari Clinic for sickle cell anemia patients. Only patients enrolled during this study period are considered eligible for inclusion in study. The following data were collected: (1) basic demographic information: name, age, gender, identification number, and contact information; (2) Personal detail like habit, diet, blood group, family history, vaccination history, rate of painful crisis, no of time hospitalization and blood transfusion before presenting for treatment at a clinic, consanguinity, etc The data were collected from patient files as well as from the electronic medical record system. We used a unique identification number for every patient instead of a name or medical record number. The data were kept confidential and stored in a safe place. All the statistical analyses were performed based on the patients who were eligible for the study. Categorical variables were summarized by frequency distribution for each categorical component (relative frequencies and percentage). Data were entered into Excel spreadsheets and all the analyses were done using a statistical package for the social sciences (SPSS). Results were reported as mean ± standard deviation for continuous variables and as counts (%) for categorical variables. Continuous variables with a normal distribution were compared using One-Way Repeated Measure Analysis of Variance. The result was significant at $p<0.05$.[15,16] On the baseline day, visit 1 means after 30 days, visit 2 means between 60 to 90 days and visit 3 means after 120 days of treatment adherence the investigation of clinical and laboratory are done. The clinicians followed the wong baker pain score scale for routine analysis of painful crises in patients. Therefore, mentioned pains score in case report file considered pain scale in individual patients. As per the pain scale score 0 is no pain, 2 mild pain, 4 medium level pain, 6 moderate level pain and 8 is severe pain 10 is very severe pain observed in patients.

**Results:** The demographic information for the enrolled 100 participants of sickle cell trait is mentioned as below in table 2. All the patients are confirmed sickle cell anemia patients having sickle cell trait confirmed through HPLC methods are only enrolled for the study.

**Table 2: Basic Demographic Information of sickle cell patients (n=100)**

| Demographics Details | | n=100 |
|---|---|---|
| **Age (years), Mean ± SD** | | 25.93 ± 13.09 |
| **Gender, n (%)** | Male | 29 (29.00) |
| | Female | 71 (71.00) |
| **Consanguinity, n (%)** | Yes | 19 (19.00) |
| | No | 81 (81.00) |
| **Habit, n (%)** | Yes (Smoking/Tobacco) | 8 (8.00) |
| **Diet, n (%)** | Both | 62 (62.00) |
| | Vegetarian | 37 (37.00) |
| **Rate of painful crisis, n (%)** | Mild | 1 (1.00) |
| | Moderate | 85 (85.00) |
| | Severe | 13 (13.00) |

The effectiveness of treatment on hemoglobin, Red blood corpuscles and reticulocytes are mentioned in following figure 1 and table 3.

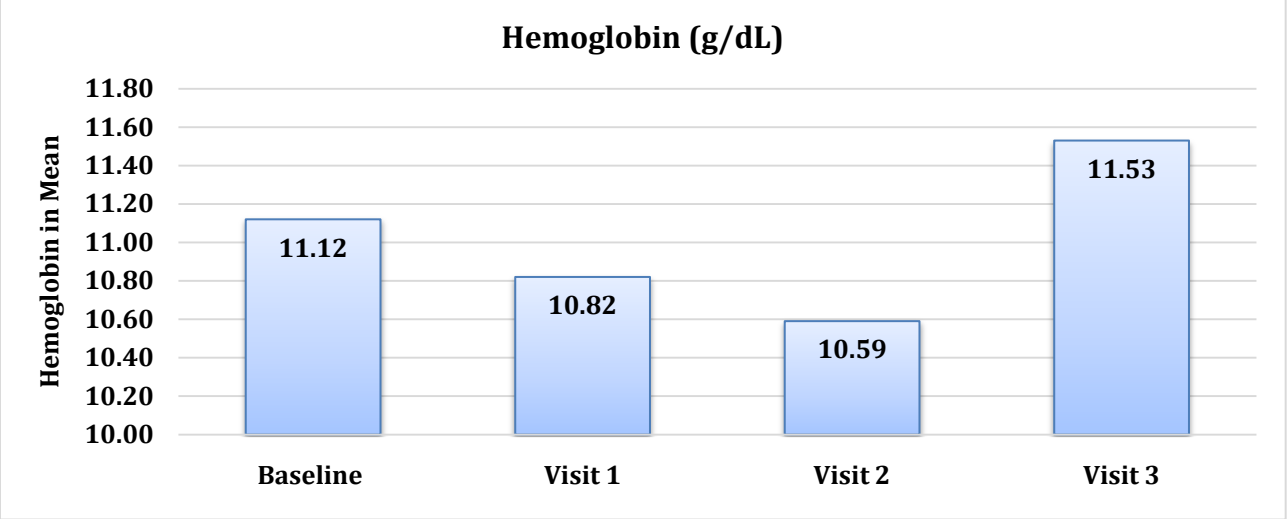


**Figure 1: Effectiveness of T-AYU-HM Premium on Hemoglobin**

**Table 3: Effectiveness of T-AYU-HM Premium on RBC and Reticulocytes**

| Variables | Baseline | Visit 1 | Visit 2 | Visit 3 | p-value |
|---|---|---|---|---|---|
| RBC (in cmm) | 4.83 ± 0.88 | 4.48 ± 0.97 | 4.13 ± 1.25 | 4.53 ± 0.72 | **<0.0001** |
| Reticulocytes (%) | 1.89 ± 1.59 | 0.84 ± 1.48 | 0.62 ± 1.24 | 0.87 ± 0.98 | **<0.0001** |

The effectiveness of T-AYU-HM Premium treatment of other hematological parameters are mentioned as below in Table 4.

**Table 4: Effectiveness of T-AYU-HM Premium on hematological parameters**

| Variables | Baseline | Visit 1 | Visit 2 | Visit 3 | p-value |
|---|---|---|---|---|---|
| WBC (/cmm) | 8284.60 ± 2754.67 | 7330.90 ± 2606.22 | 7255.70 ± 2926.35 | 7758.90 ± 2075.78 | **0.014** |
| Platelet (/uL) | 338890.00 ± 110195.78 | 299110.00 ± 118467.82 | 281350.00 ± 133397.08 | 304430.00 ± 87818.60 | **0.0003** |
| MCHC (g/dL) | 32.74 ± 1.72 | 32.80 ± 5.00 | 31.56 ± 8.20 | 33.93 ± 1.47 | **0.004** |
| MCH (pg) | 23.42 ± 3.73 | 24.19 ± 6.02 | 24.55 ± 7.71 | 26.41 ± 4.51 | **<0.0001** |
| MCV (fl) | 71.35 ± 9.23 | 71.48 ± 16.28 | 71.71 ± 22.33 | 76.67 ± 11.73 | **0.0065** |
| PCV (%) | 33.63 ± 6.30 | 32.27 ± 7.22 | 31.58 ± 10.13 | 34.15 ± 4.83 | **0.0052** |
| Neutrophil (%) | 60.44 ± 11.42 | 58.90 ± 14.88 | 58.43 ± 18.92 | 62.02 ± 11.68 | 0.174 |
| Eosinophil (%) | 5.25 ± 8.24 | 4.77 ± 7.24 | 4.43 ± 6.74 | 4.35 ± 7.17 | 0.066 |
| Basophil (%) | 0.05 ± 0.36 | 0.12 ± 0.61 | 0.10 ± 0.61 | 0.01 ± 0.10 | 0.193 |
| Lymphocyte (%) | 33.79 ± 10.29 | 33.11 ± 11.41 | 29.69 ± 11.78 | 32.83 ± 9.53 | **0.01** |
| Monocytes (%) | 0.52 ± 2.12 | 0.89 ± 2.82 | 0.90 ± 3.19 | 0.71 ± 2.96 | 0.224 |

The effectiveness of T-AYU-HM Premium to assess the overall health-based profile parameters like SpO2, Pulse rate, Serum bilirubin and weight are also observed at schedule visit are mentioned as given below in table 5.

**Table 5: Effectiveness of T-AYU-HM Premium on other vitals parameters**

| Variables | Baseline | Visit 1 | Visit 2 | Visit 3 | p-value |
|---|---|---|---|---|---|
| S.billirubin (mg/dL) | 1.05 ± 1.01 | 0.50 ± 1.35 | 0.26 ± 0.58 | 0.45 ± 0.60 | **<0.0001** |
| Direct (mg/dL) | 0.49 ± 0.48 | 0.25 ± 0.75 | 0.11 ± 0.27 | 0.21 ± 0.29 | **<0.0001** |
| Indirect (mg/dL) | 0.55 ± 0.58 | 0.25 ± 0.63 | 0.15 ± 0.34 | 0.25 ± 0.34 | **<0.0001** |
| SpO2 (%) | 98.29 ± 1.37 | 98.65 ± 0.96 | 98.42 ± 1.46 | 98.83 ± 0.71 | **0.0010** |
| Pulses (per minute) | 96.30 ± 18.22 | 91.04 ± 15.71 | 92.16 ± 17.60 | 92.22 ± 15.03 | **0.0206** |
| Weight (in Kg) | 46.40 ± 16.68 | 45.89 ± 15.83 | 46.11 ± 15.71 | 46.36 ± 15.37 | 0.2527 |

The effectiveness of T-AYU-HM Premium on various major and minor clinical parameters are also observed and its results are mentioned in given below table 6 and 7.

**Table 6: Effectiveness of T-AYU-HM Premium on major clinical parameters**

| Parameters, n (%) | Score | Baseline | Visit 1 | Visit 2 | Visit 3 |
|---|---|---|---|---|---|
| ***Plihodar* (Splenomegaly)** | **0** | 62 (62) | 83 (83) | 89 (89) | 94 (94) |
| | **2** | 25 (25) | 14 (14) | 8 (8) | 6 (6) |
| | **4** | 12 (12) | 3 (3) | 3 (3) | 0 (0) |
| | **8** | 1 (1) | 0 (0) | 0 (0) | 0 (0) |
| ***Kamala* (Jaundice)** | **0** | 92 (92) | 94 (94) | 97 (97) | 99 (99) |
| | **2** | 2 (2) | 6 (6) | 1 (1) | 1 (1) |
| | **4** | 5 (5) | 0 (0) | 2 (2) | 0 (0) |
| | **6** | 1 (1) | 0 (0) | 0 (0) | 0 (0) |
| ***Panduta* (Pallor)** | **0** | 75 (75) | 90 (90) | 93 (93) | 100 (100) |
| | **2** | 16 (16) | 7 (7) | 5 (5) | 0 (0) |
| | **4** | 7 (7) | 2 (2) | 2 (2) | 0 (0) |
| | **6** | 2 (2) | 1 (1) | 0 (0) | 0 (0) |
| ***Durbalya* (General weakness)** | **0** | 29 (29) | 81 (81) | 90 (90) | 97 (97) |
| | **2** | 39 (39) | 15 (15) | 5 (5) | 1 (1) |
| | **4** | 29 (29) | 4 (4) | 5 (5) | 2 (2) |
| | **6** | 3 (3) | 0 (0) | 0 (0) | 0 (0) |
| ***Hardadrava* (Palpitation)** | **0** | 83 (83) | 97 (97) | 94 (94) | 95 (95) |
| | **2** | 13 (13) | 2 (2) | 5 (5) | 5 (5) |
| | **4** | 4 (4) | 1 (1) | 1 (1) | 0 (0) |
| ***Sarma* (Fatigue)** | **0** | 54 (54) | 94 (94) | 92 (92) | 96 (96) |
| | **2** | 33 (33) | 5 (5) | 5 (5) | 2 (2) |
| | **4** | 12 (12) | 1 (1) | 3 (3) | 2 (2) |
| | **6** | 1 (1) | 0 (0) | 0 (0) | 0 (0) |
| ***Angamarda* (Bodyache)** | **0** | 22 (22) | 74 (74) | 85 (85) | 91 (91) |
| | **2** | 33 (33) | 21 (21) | 12 (12) | 7 (7) |
| | **4** | 40 (40) | 5 (5) | 3 (3) | 2 (2) |
| | **6** | 5 (5) | 0 (0) | 0 (0) | 0 (0) |

**Table 7: Effectiveness of T-AYU-HM Premium on minor clinical parameters**

| Parameters, n (%) | Score | Baseline visit | Visit 1 | Visit 2 | Visit 3 |
|---|---|---|---|---|---|
| ***Brahm* (Giddiness)** | **0** | 90 (90) | 93 (93) | 100 (100) | 100 (100) |
| | **2** | 4 (4) | 6 (6) | 0 (0) | 0 (0) |
| | **4** | 2 (2) | 0 (0) | 0 (0) | 0 (0) |
| | **6** | 3 (3) | 1 (1) | 0 (0) | 0 (0) |
| | **8** | 1 (1) | 0 (0) | 0 (0) | 0 (0) |
| ***Angamarda* (Backache)** | **0** | 41 (41) | 81 (81) | 85 (85) | 89 (89) |
| | **2** | 23 (23) | 12 (12) | 12 (12) | 10 (10) |
| | **4** | 29 (29) | 6 (6) | 3 (3) | 1 (1) |
| | **6** | 6 (6) | 1 (1) | 0 (0) | 0 (0) |

| | | | | | |
|---|---|---|---|---|---|
| | **8** | 1 (1) | 0 (0) | 0 (0) | 0 (0) |
| ***Ananashotha* (Puffiness on face)** | **0** | 91 (91) | 97 (97) | 95 (95) | 97 (97) |
| | **2** | 4 (4) | 3 (3) | 5 (5) | 3 (3) |
| | **4** | 5 (5) | 0 (0) | 0 (0) | 0 (0) |
| ***Udara shool* (Abdominal colic)** | **0** | 66 (66) | 90 (90) | 91 (91) | 95 (95) |
| | **2** | 12 (12) | 6 (6) | 5 (5) | 4 (4) |
| | **4** | 14 (14) | 3 (3) | 4 (4) | 1 (1) |
| | **6** | 8 (8) | 1 (1) | 0 (0) | 0 (0) |
| ***Agnimandhya* (Loss of appetite)** | **0** | 75 (75) | 96 (96) | 94 (94) | 98 (98) |
| | **2** | 15 (15) | 4 (4) | 2 (2) | 2 (2) |
| | **4** | 10 (10) | 0 (0) | 4 (4) | 0 (0) |
| **Headache** | **0** | 79 (79) | 90 (90) | 95 (95) | 96 (96) |
| | **2** | 16 (16) | 8 (8) | 5 (5) | 4 (4) |
| | **4** | 3 (3) | 2 (2) | 0 (0) | 0 (0) |
| | **6** | 1 (1) | 0 (0) | 0 (0) | 0 (0) |
| | **8** | 1 (1) | 0 (0) | 0 (0) | 0 (0) |
| **Chest Syndrome** | **0** | 90 (90) | 95 (95) | 93 (93) | 98 (98) |
| | **2** | 3 (30) | 4 (4) | 6 (6) | 2 (2) |
| | **4** | 6 (6) | 1 (1) | 1 (1) | 0 (0) |
| | **6** | 1 (1) | 0 (0) | 0 (0) | 0 (0) |
| **AVNF** | **0** | 94 (94) | 94 (94) | 94 (94) | 96 (96) |
| | **2** | 1 (1) | 4 (4) | 5 (5) | 3 (3) |
| | **4** | 1 (1) | 1 (1) | 0 (0) | 0 (0) |
| | **6** | 0 (0) | 1 (1) | 1 (1) | 1 (1) |
| | **8** | 4 (4) | 0 (0) | 0 (0) | 0 (0) |
| **Priapism** | **0** | 100 (100.00) | 100 (100) | 100 (100) | 100 (100) |

Effectiveness of T-AYU-HM Premium on no of times blood transfusion and hospitalization during the treatment period has been mentioned in below table 6.

**Table 8: Effectiveness of Treatment of T-AYU-HM Premium tablets**

| **Parameters** | **Baseline visit (Day 0)** | **Visit 3 (Day 120)** |
|---|---|---|
| No of Hospitalization | 1.23 ± 2.09 | 00 |
| Blood transfusion | 0.24 ± 1.32 | 00 |
| Data are expressed in Mean ± SD | | |

## DISCUSSION

Sickle cell anemia is an autosomal recessive condition in which red blood cells can take on the appearance of a sickle, especially when exposed to hypoxia. These could result in problems from the breakdown of sickle cells, decreased perfusion from artery obstruction brought on by sickle cell clumping, or toxic consequences from processing ruptured red blood corpuscles. Sickle cell anemia patients frequently experience *Panduta* (Pallor) and *Durbalaya* (general weakness), *Kamala* (jaundice), discomfort (from vascular blockage), and *Plihodar* (splenomegaly). The medications now being utilized either help restore red blood cells or treat pain symptoms (analgesics) (hematinics). None of these can lessen the need for hospitalization and blood transfusions or offer long-term respite from the disease's complications.[9]

The results clearly mentioned that during the entire treatment the cellular lysis has been prevented and further complications associated with lysis are avoided. Major and minor complaints are resolved gradually overtime with treatment with T-AYU-HM Premium. Therefore, we observed no patients progressed towards any major complications due to

sickling or cellular lysis during the entire treatment period. The significant improvement in mean corpuscles volume (MCV) suggests improvement in iron-based oxygen affinity in the patients. The ingredient incorporated as mentioned earlier possess iron as a potential source in the formulation. This clearly means the formulation not only sustained cellular lysis through acting on cell membrane or ion channel but it also solved intracellular problems associated in anemia.[14] Other blood cell parameters are completely within normal range which clearly suggest that there were no inflammation or injury or triggered event induced any complications. During the entire treatment period no untoward reactions or response were recorded in any case report file. During evaluating the serum billirubin level it can be confirmed that there was no hemolysis-based burden on liver and appears absolute normal and improved (Before: 1.05 ± 1.01; after: 0.45 ± 0.60mg/dL) in functions. Even the occurrence of splenomegaly was found to reduce significantly. Even in table 2 results of red blood corpuscles and reticulocytes suggested that there is definite no acute red blood corpuscles destruction. Reticulocyte count are used as vital marker to predict sickling induced complications. The pulses, oxygen saturation, and weight of patients' remains sustained and no abnormal changes have been observed. Sickle cell anemia patients' major and minor complaints showed a considerable improvement when treated with T-AYU-HM Premium, according to an analysis of the complaints. The majority of patients reported a considerable decrease in the intensity and frequency of pain episodes, which was one of the main advantages of T-AYU-HM Premium. This would result in a dramatic improvement in the patients' day-to-day functionality.

Overall, the results suggest that T-AYU-HM Premium is effective in improving the hemoglobin (gm %) and in fact significantly improving the clinical status of patient's sickle cell anemia. In addition to this, T-AYU-HM Premium was also found to be significantly better in alleviating the complications of sickle cell anemia like episodes of Pain and splenomegaly. Currently, there is a great need of any drug that canbe safe, effective, and easily available in the management of sickle cell anemia. T-AYU-HM Premium is an alternative system class of formulation so patients' compliance can be better expected.

## CONCLUSION

The effect of T-AYU-HM Premium treatment in sickle cell trait patients suggests it is safe and effective. There was no adverse effect found from the observational study. During the entire study period no single blood transfusion or hospitalization is required suggest that treatment prevents further cellular lysis process. The significant improvement in rate and frequency of painful crisis might suggest improvement in pain related quality of life in patients. This treatment of T-AYU-HM Premium was a safe, cost-effective and exhibit therapeutic potential in the management of sickle cell trait patients.

## ACKNOWLEDGEMENT

Authors express sincere thanks to independent ethics committee, ATBU Harita Pharmaceuticals Pvt Ltd for all the required support and assistance.

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**Cite this article as:**
Atul Desai, Kavita Desai, Hemshree Desai, Rutvij Desai, Chirag Desai. Clinical evaluation of T-AYU-HM Premium in Sickle cell Anemia patients: A retrospective study. International Journal of Ayurveda and Pharma Research. 2022;10(Suppl 2):28-35.
https://doi.org/10.47070/ijapr.v10iSuppl2.2554
***Source of support: Nil, Conflict of interest: None Declared***

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