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

International Journal of Ayurveda and Pharma Research

Case Study

STUDY OF SAFETY AND EFFECT OF T-AYU-HM PREMIUM IN SICKLE CELL ANEMIA PATIENT: A CASE STUDY

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Article info

Article History:
Received: 25-07-2022
Revised: 05-08-2022
Accepted: 19-08-2022

KEYWORDS:
Sickle cell anaemia, T-AYU-HM Premium, blood transfusion.

ABSTRACT

Sickle cell anaemia is a type of haemoglobin disorder causing morbidity and mortality in many countries. The disease is incurable and therefore requires symptomatic management to improve quality of life. Because the alternative system of medicine can play a significant role in the management of quality of life in sickle cell anaemia, lot many combinations and formulations are attempted across many countries. Unfortunately, very few have reached a preclinical and clinical research level. In the current case study, T-AYU-HM Premium was evaluated as per the standard parameters, and a clinical evaluation considering its effect and safety was performed in this case report of a 24-year-old male with a history of sickle cell disease in hereditary. History was 8 times blood transfusion and 7 times hospitalization in past two year. He was infected with covid-19 and hospitalized, recovered with T-AYU-HM Premium only. Next month because of joint pain, fever, and weakness he visited the daycare clinic. On complete physical and laboratory examination he was started on T-AYU-HM Premium 300mg two tablets twice a day. During 6 months of treatment, he had complained of pain only thrice for which analgesics were prescribed, and no blood transfusion was required. During this 6 month period, there is a remarkable improvement in his haemoglobin, red blood corpuscles, white blood cells, and platelets. There were no untoward complaints from him suggesting that T-AYU-HM Premium exhibited its potential in sustaining the cellular integrity and thereby preventing the lysis of red blood corpuscles. The improvement in laboratory parameters, clinical parameters and established studies indicated that T-AYU-HM Premium is safe and exhibit an observational effect on red blood corpuscles of sickle cell anaemia patient.

INTRODUCTION

Sickle cell anaemia is a type of haemoglobin disorder causing morbidity and mortality in many countries. The disease is incurable and therefore requires symptomatic management to improve quality of life.[1-3] Many previous studies have mentioned that sickle cell anaemia disease is *Bijadushti* (genetic deformity), clinically compared with *Panduroga* (anaemia) with *Adibala parivrutta Vyadhi* (hereditary disorder).

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https://doi.org/10.47070/ijapr.v10i8.2498

The previous literature on Ayurveda suggested that the subsequent *Aama* generation (premature RBC destruction), *Tridosha prakopa* and *Dhatukshaya* worsen the overall illness.[4] Because the alternative systems of medicine can play a significant role in the management of quality of life in sickle cell anaemia, lot many combinations and formulations are attempted across many countries. Unfortunately, very few have reached a preclinical and clinical research level.[5]

T-AYU-HM Premium is a traditional Ayurvedic medicine designed with timely tested herbs and minerals. Each 300mg tablet contains ingredients are mentioned in following table 1. The formulation's safety was evaluated through preclinical testing like acute oral toxicity study up to the dose of 5000mg/kg,[6] and the no observed adverse effect level (NOAEL) is evaluated from sub-chronic toxicity study the dose up to 1250mg/kg body weight when administered orally for 90 days in both the sexes of

Swiss Albino mice.[7] Further the physicochemical and shelf life evaluation of formulation was also done for standardization batches. When homozygous sickle cells were deoxygenated in a test tube during Emmel's test, T-AYU-HM Premium (25g/ml, 50g/ml, 100g/ml, and 500g/ml) inhibited sickling in a dose-dependent manner. Mechanistic analyses showed that the presence of 50g/ml, 100g/ml, and 500g/ml of T-AYU-HM Premium considerably reduced the t-BOOH-induced oxidative haemolysis and met-haemoglobin production in a dose-dependent manner. Membrane stabilization activity measured by the osmotic fragility test significantly increased stabilization when 50g/ml, 100g/ml and 500g/ml of T-AYU-HM Premium were present.[8] The formulation was evaluated clinically (CTRI/2020/08/027477) on covid-19 mild to moderate patients and found a potential effect on oxygen saturation, Erythrocyte sedimentation rate, C-reactive protein, and D-Dimer level.[9] The formulation was evaluated by four experimental models that exhibited immunomodulatory activity as an immunostimulant.[10] There are already many reported case report studies published in previous time duration exploring the therapeutic potential of T-AYU-HM Premium alone as well as when used in an integrated treatment approach.[11]

Table 1: Product T-AYU-HM Premium detail

Product	**T-AYU-HM™ Premium**
Appearance	Brown color tablet
Manufacture by	ATBU Harita Pharmaceuticals Pvt.Ltd, Gujarat
Product Ingredients	Each 300 mg tablet is composed of Calyx of Mica (25mg) Calyx of iron (12.5mg) *Terminalia chebula* (25mg) *Zingiber officinale* (25mg) *Asparagus racemosus* (25mg) Punica granatum (12.5mg) *Myristica fragrans* (25mg) *Piper longum* (37.5mg) *Tinospora cordifolia* (37.5mg) *Leptadiniareticlata* (37.5mg)
Storages condition	Store in dry and cool place, Keep away from direct sunlight. Do not refrigerate.

Case Report

The objective of this case report presentation is to highlight to scientific communities that the safety of T-AYU-HM Premium as required by standard guidelines was already established. Even the effect of T-AYU-HM Premium in sickle cell anaemia patients is discussed in this case report with prior consent received from the patient consent for the utilization of data, the case study progressed to obtain more information for the betterment of the community in the future.

In the current case study, a 24-year-old male with a history of sickle cell disease in hereditary visited the daycare clinic because of joint pain, fever, and weakness. His history was infected with Covid-19 and hospitalized. He had 2 times blood transfusions meanwhile and overall 8 times in the last two year. He was hospitalized 7 times in past two years due to painful crises. During the visit his weight was 46.6kg, pulses are 83 beats/ minute, spO2 was 99%, and Blood pressure was 122/68mmHg. He had complete immunization history including covid-19. He had complaints of painful crises for 5 days a month impacting joint pain like knee, legs, and hip during episodes of pain. He often took folic acid for his condition. There are 5 family members but no consanguinity among parents. Before proceeding further laboratory investigation was advised. He was infected with covid-19 on 07/01/2022 and started integrated treatment of T-AYU-HM Premium. He adhered the guidelines and recovered within 21 days. His laboratory report during the recovery period is mentioned below in table 2 along with present day report.

Table 2: Clinical Parameters of Baseline day Visit to Clinic

Investigation (Mr X)	**10/01/2022**	**02/02/2022**
Hb (gm/dl)	8..6	10.2
RBC (m/cmm)	4.13	4.24
WBC (/cmm)	10300	5500

Platelets (per microliter)	207000	141000
ESR (mm/hr)	-	08
CRP (mg/l)	-	0.6
D-dimer (ng/ml)	-	127
Neutrophils (%)	77	58
Lymphocytes (%)	01	37

He was prescribed T-AYU-HM Premium 300 mg two tablets twice a day for 07 days. On the next scheduled visit, his clinical complaints were resolved so the prescription was refilled for the next 15 days. Considering his medication-taking behaviour, adherence and compliance to the treatment he completed almost six months adhering to T-AYU-HM Premium. During these 6 months of medication adherence, he had experienced a painful crisis only thrice for which he has prescribed analgesics symptomatically. He didn't require a blood transfusion and hospitalization for the last 6 months too. He is capable enough to manage his tailoring business due to improvement in his clinical conditions. His subsequent laboratory parameters of the scheduled visit are mentioned in following table 3.

Table 3: Laboratory Results of Subsequent Visits

Investigation (Mr X)	**19/03/22**	**20/06/2022**
Hb (g/dl)	9.6	8.53
RBC (m/cmm)	4.26	4.62
WBC (/cmm)	5500	8180
Platelets (per microliter)	155000	187000
ESR (mm/hr)	08	5
CRP (mg/l)	11.5	-
D-dimer (ng/ml)	-	-
Neutrophils (%)	59	22
Lymphocytes (%)	37	71

DISCUSSION

The effect of T-AYU-HM Premium on red blood corpuscles suggests it sustained the cellular integrity and prevent cellular lysis. During the treatment period, the haemoglobin remains within the anticipated range of sickle cell patients (between 6-10g/dl). The potential of an increase in blood viscosity also increases with an increase in haemoglobin. Sickle cell disease patients have high viscosity than the normal population. An increase in hematocrit and sickling of red blood corpuscles cause a substantial rise in viscosity. Red blood corpuscles rheology might make it possible to safely raise hemoglobin without running the risk of problems from hyperviscosity. Therefore, when deciding how much haemoglobin may be raised safely in sickle cell disease patients, the mechanism and time it takes for a medication to start working may be crucial factors to take into account. The major clinical observation in the patient was 8 times blood transfusions during the past one year. The brief indications for patients with sickle cell anaemia required transfusion are mentioned in table 4

Table 4. Indication for Blood transfusion in sickle cell disease patients [12]

Indication	**Type of transfusion**
Acute transfusion indication	
aplastic anemia crisis	Simple transfusion
acute splenic sequestration	Simple transfusion
Acute clinical stroke	Exchange transfusion
Intra-hepatic cholestasis	Simple or exchange transfusion
Acute chest syndrome	Simple or exchange transfusion
Acute multi-organ failure	Simple or exchange transfusion
Surgeries lasting >1 hour and require general anesthesia	Simple or exchange transfusion

Pregnancy	Simple or exchange transfusion
Chronic Transfusion Indication	
Primary stroke prevention	Simple or exchange transfusion
Secondary stroke prevention	Simple or exchange transfusion
Frequent Vaso-occlusive crisis	Simple or exchange transfusion

From previous studies, it is clear that the most common cause of hospitalization and urgency of blood transfusion or parenteral treatment is an acute painful crisis. Moderate to severe level painful crises hamper the quality of life in patients with sickle cell anaemia too. But on the other side, previous studies have also reported that transfusions can result in sickle cell events such as acute lung deterioration, stroke, and pain crises. These are brought on in part by elevated blood pressure and blood viscosity. These incidents can be reduced with diuretic medication and careful monitoring of the transfusion volume and vital signs.[13] In the current case report the patient exhibited remarkable improvement as there is not a single time to require a blood transfusion. It is observed that when painful crises are reduced overall sickling- induced complications are controlled and thereby requirement of emergency hospitalization and blood transfusion can also be reduced. Pain is one of the most common complications and the top reason for hospitalization or emergency visits in sickle cell patients. This pain can start at any time depending on triggering factors and last for any length of period. Painful crises are the main reason for the high medical utilization and expanses amongst sickle cell disease patients.[14] In India socioeconomic conditions, lack of information, lack of financial resources, and treatment affordability for pain-related hospitalization or cost-wise burden are not studied extensively to date.[15] In the current case report patient had a painful crisis only thrice in six months of medication adherence. The elevated C-reactive protein on the scheduled visit date of 19/03/2022 represents a painful crisis. Therefore expanses towards analgesics and hospitalization are minimized. For Indian patients' expanses of treatment, that too for lifelong disorder matters financially and psychologically.

CONCLUSION

Sickle cell anaemia is a type of haemoglobin disorder causing morbidity and mortality in India. Considering the rising cost of healthcare, a haemoglobin disorder demands a safe and affordable management solution. T-AYU-HM Premium tablets exhibit safety and efficacy at a preclinical level as well as clinical level. Previously reported case reports and immunomodulatory activity offers more documented pieces of evidence. In the present case, during six months of medication adherence patient didn't experience any untoward reactions; clinical parameters present the effect of T-AYU-HM Premium on sickle cell disease patients. The patient experiences remarkable improvement without frequent painful crisis, no blood transfusion requirement, and no hospitalization indicate it is safe and effective in sickle cell anaemia patients.

Acknowledgement: Authors express their sincere thanks to a patient for the utilization of data; the case study progressed to obtain more information for the betterment of the community in the future

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Cite this article as:
Atul Desai. Study of Safety and Effect of T-Ayu-Hm Premium in Sickle Cell Anemia Patient: A Case Study. International Journal of Ayurveda and Pharma Research. 2022;10(8):104-108.
https://doi.org/10.47070/ijapr.v10i8.2498
Source of support: Nil, Conflict of interest: None Declared

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