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Case Report

Integrative management of chronic leg ulcer in Sickle cell disease: A case report on T-AYU-HM Premium and ACUPEN Therapy

Atul Desai[1]*, Kavita Desai[1], Hemshree Desai[2], Rutvij Desai[3], Chirag Desai[4], Jital Desai[5], Rajesh Mahida[6]

1. Dhanvantari Clinic, Ayurveda Healthcare and Research Centre, Vyara. Gujarat. India.
2. Master's Students in Public Health; University of Glasgow, Scotland, United Kingdom.
3. MD, Manila Central University; Philippines.
4. Department of Pharmacology, ROFEL Shri G M Bilakhia College of Pharmacy, A constituent college of Rajju Shroff ROFEL University (RSRU), Vapi. India.
5. Department of Pharmaceutical analysis, Parul Institute of Pharmacy, Parul University, Vadodara. India.
6. MBBS, MS, Love and Care Hospital, Vyara. India.

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Abstract

Background: Sickle cell disease (SCD) is associated with chronic complications, including non-healing leg ulcers. These are difficult to manage due to factors like poor perfusion, hemolysis, oxidative stress, and malnutrition. This case report explores the role of two Ayurvedic formulations, T-AYU-HM Premium and ACUPEN, in treating chronic leg ulcers in an SCD patient. Case Presentation: An 18-year-old male with SCD presented with multiple chronic ulcers on the left ankle and tibia. Associated symptoms included septic discharge, severe anemia (Hb: 6.25 g/dL), elevated CRP (31.16 mg/dL), leukocytosis, and high bilirubin. He had intermittently used T-AYU-HM since 2010. A comprehensive treatment plan including T-AYU-HM Premium, ACUPEN (oral and topical), antibiotics, analgesics, and hematinics was initiated. Outcome: By November 2024, significant improvements were observed: hemoglobin increased to 10.63 g/dL, CRP dropped to 4.8 mg/dL, and the ulcers healed with scar formation. Inflammation reduced significantly, dorsiflexion improved, and both bilirubin and reticulocyte levels stabilized. Discussion: The combination of T-AYU-HM Premium and ACUPEN facilitated hematological recovery and accelerated wound healing. T-AYU-HM supported erythropoiesis, while ACUPEN enhanced microcirculation and reduced edema. Both addressed systemic and local ulcer pathogenesis. Conclusion: Integrating Ayurvedic therapies with conventional treatments may effectively manage SCD-related leg ulcers, but further studies are needed to confirm these findings.

Keywords: Sickle Cell Disease, Leg Ulcer, T-AYU-HM Premium, ACUPEN, Chronic wound healing

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Introduction

Leg ulcers are a debilitating and common complication of sickle cell disease (SCD), particularly in patients with the most severe genotype, homozygous hemoglobin SS (HbSS). These chronic wounds frequently develop around the ankles—especially near the medial and lateral malleoli—and represent a significant source of morbidity, pain, and reduced quality of life in affected individuals. (1, 2) Sickle cell disease is an inherited hemolytic anemia caused by a point mutation in the β-globin gene, leading to the production of abnormal hemoglobin S (HbS). Under hypoxic or other stress conditions, HbS polymerizes, causing red blood cells to assume a rigid, sickle-like shape.(3) These deformed erythrocytes are prone to hemolysis and have increased adhesiveness and reduced deformability, contributing to microvascular occlusion. This vaso-occlusive phenomenon, combined with repeated episodes of ischemia-reperfusion injury, plays a central role in the pathogenesis of various SCD complications, including cutaneous leg ulcers. (4)

This case report highlights the clinical presentation, diagnostic findings, and integrated management approach for a patient with sickle cell disease complicated by chronic leg ulceration. Emphasis is placed on multidisciplinary treatment strategies aimed at promoting wound healing and preventing recurrence.

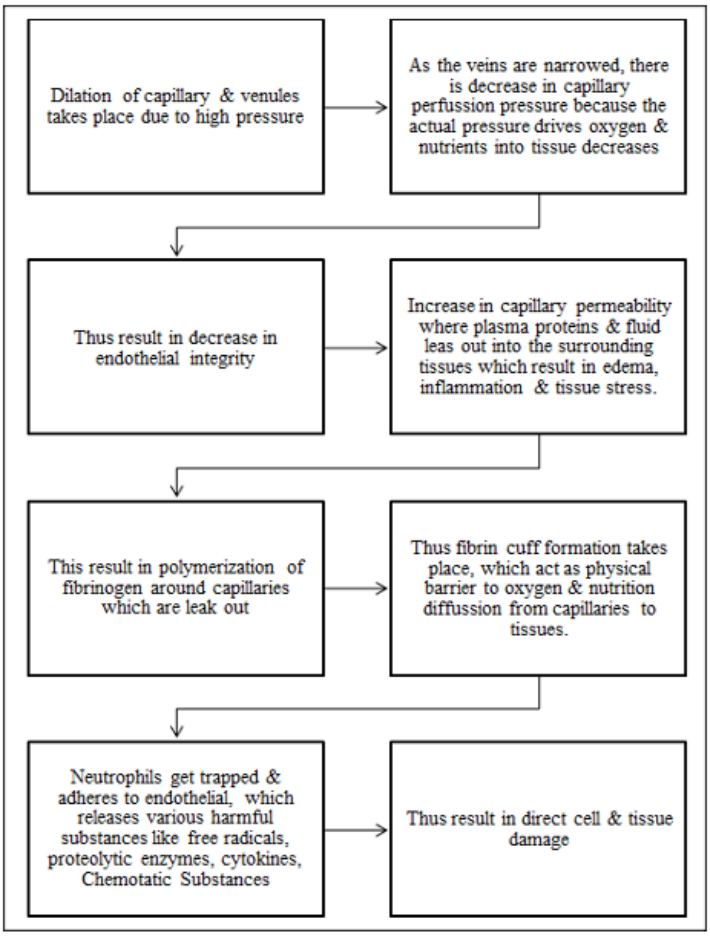
Understanding these multifaceted contributors is essential for guiding a comprehensive and multidisciplinary management approach, as illustrated in the case below. The development of leg ulcers in patients with sickle cell disease (SCD) is multifactorial and complex. One key mechanism involves chronic intravascular hemolysis, which leads to reduced levels of nitric oxide (NO)—a critical mediator of endothelial function. The resulting NO

*** Corresponding Author:**
Atul Desai
Dhanvantari Clinic,
Ayurveda Health Care and Research Centre,
Vyara, Gujarat. 394650. India.
Email Id: dratuldesai@rediffmail.com

deficiency promotes vasoconstriction, endothelial dysfunction, and impaired blood flow to peripheral tissues.(5) This chronic hypoperfusion of the epidermal and subcutaneous layers hinders effective tissue repair and regeneration.

In addition to hemolysis-related vascular changes, anemia reduces oxygen delivery to tissues, while local trauma and secondary infections further compromise skin integrity and delay wound healing.(6) Several modifiable and non-modifiable risk factors also contribute to ulcer development, including genetic predisposition, low socioeconomic status, poor nutritional status, and limited access to comprehensive healthcare services.(7) These factors not only increase the risk of ulcer formation but also exacerbate their severity and chronicity in individuals with SCD. Figure 1: Schematic representation of possible pathogenesis of leg ulcer in sickle cell disease. (8-11)

Figure 1: Possible Pathogenesis of Leg ulcer



T-AYU-HM Premium is a herbo-mineral formulation developed for the management of sickle cell anemia, designed to enhance erythropoiesis, reduce hemolysis, and support hematological and immunological functions. The formulation comprises mineral and herbal ingredients—*Abhraka Bhasma* (mica calyx), *Loha Bhasma* (iron calyx), *Terminalia chebula* (fruit), *Zingiber officinale* (rhizome), *Asparagus racemosus* (root), *Punica granatum* (fruit), *Myristica fragrans* (seed), *Piper longum* (fruit), *Tinospora cordifolia* (stem), *and Leptadenia reticulata* (root)—collectively contributing to its therapeutic potential. It combines traditional *Rasayana* (rejuvenative) principles with targeted therapeutic action on red cell regeneration and systemic oxidative stress. (12-14)

ACUPEN is a polyherbal formulation specifically developed for the management of inflammatory and chronic wound conditions, including leg ulcers. The formulation comprises medicinal plant parts—*Commiphora mukul* (gum), *Aloe vera* (leaf), *Boerhavia diffusa* (root), *Ricinus communis* (root), *Apium leptophyllum* (root), *Myristica fragrans* (seed), and *Triphala* (fruit)—all possessing established analgesic and anti-inflammatory properties, contributing to its therapeutic potential. It exhibits anti-inflammatory, analgesic, antimicrobial, and angiogenic properties, supporting both systemic immune modulation and local tissue repair.(15-17)

Both formulations are manufactured by ATBU Harita Pharmaceuticals, combining classical Ayurvedic knowledge with modern phytopharmacological principles to provide integrative support in chronic, multifactorial disorders such as sickle cell disease and associated complications like leg ulcers.

Case Details

Patient Consent: The authors sincerely thank the patient and their family for granting written informed consent to use the clinical details and images for the purposes of academic publication and contributing to the improvement of medical knowledge and patient care, in accordance with CARE guidelines.

Site of Study: Dhanvantari Clinic, Ayurveda Healthcare and Research Centre, Vyara-Gujarat

Patient Profile: An 18-year-old male from Sakli, Maharashtra, with a known history of sickle cell disease (SCD). He has been on T-AYU-HM Premium since 2010, but with irregular compliance. In February 2024, the patient developed a wound on the left ankle. Initially, he sought treatment from a surgeon.On 15th July 2024, during a Dhanvantari Clinic visit for hepatic crisis management, clinical examination revealed a septic draining discharge at the left tibiotalar joint, with inflammation involving the tibia, medial malleolus, and talus. The patient was unable to dorsiflex (pull foot upward) due to pain and pus discharge. He was presented with associated clinical features like fever, cold and cough, pain in back and shoulder, sickle cell crisis episodes. During presentation, his vital signs were notable for a pulse rate of 130 beats per minute (tachycardia), blood pressure of 110/68 mmHg (within normal limits), oxygen saturation (SpO_2) of 97% on room air, and a body weight of 45.2 kg, indicating a possible low body mass index consistent with chronic illness. He was advised for laboratory investigation for better clinical implications to manage the conditions. His laboratory details are mentioned in below table 1.

Based on his laboratory evaluation the patient was managed with a combination of systemic and local therapies to address the chronic leg ulcer and associated complications. T-AYU-HM Premium (300 mg twice daily Tablet) was continued to help reduce sickling and hemolysis. Local wound care included the application of a topical ointment (ACUPEN) twice daily to control infection. Systemic antibiotic therapy with oral cefixime (200 mg twice daily) was initiated to treat underlying bacterial infection. Supportive treatment involved paracetamol for pain and fever management, and gastrointestinal protection with a combination of domperidone (10 mg) and rabeprazole (20 mg) to prevent side effects of medications. Additionally, folic acid supplementation was provided to support erythropoiesis. The integrative approach aimed to control infection, accelerate wound healing, and address sickle cell disease complications.

Table 1: Laboratory investigation of patient on admission to clinic

TEST	15-07-24	Reference /Unit
Hemoglobin (gm/dl)	6.25	13.5-17.0 gm%
Red blood corpuscles(RBC) (/ cmm)	2.67	4.6-6.2 mill/cmm
White blood cells (WBC) (/ cmm)	64050	4000-10000/cmm
Platelet (/cmm)	416000	1.5-4.0 lac/cmm
MCHC (g/dl)	34.72	32-36 %
MCH (pg)	23.40	27-31 pg
MCV (fl)	67.41	80-96 fL
PCV (%)	18	40-54 %
Neutrophil (%)	80	55-70 %
Eosinophil (%)	6	01-05 %
Basophils (%)	0	0-01 %
Lyphocytes (%)	13	20-40 %
Monocytes (%)	1	02-08 %
ESR (mm/hr)	39	<10 Mm/hr [Westergren]
C-reactive protein (CRP) (mg/ dL)	31.16	< than 6.00 mg/dL
Reticulocutes (%)	5.0	%
Corrected Reti.Cou	2.00	%
Reticulocyte Production Index	0.80	%
IRF-Immature Retic. Fraction	23.50	%
Billirubin Total (mg/dl)	3.2	0.0-1.0 mg/dL
Billirubin Direct (mg/dl)	1.2	Upto 0.3 mg/dL
Billirubin Indirect (mg/dl)	2.0	0.1-1.0 mg/dL

On follow-up visits, the patient's vital signs showed positive trends indicating a favourable response to treatment. Oxygen saturation improved from 98% to 100%, reflecting better oxygenation. The pulse rate stabilized from a high 130 bpm initially to 67 bpm at the first follow-up and slightly increased to 75 bpm on the second visit, remaining within normal limits. Blood pressure decreased from 110/82 mmHg to 98/72 mmHg, suggesting improved hemodynamic status. The patient's weight remained relatively stable, with a minor decrease from 47 kg to 46.8 kg, indicating maintained nutritional status during treatment. Overall, these vital signs reflect clinical improvement and stabilization. His follow up visit clinical information are mentioned in below table-2.

Patient Perspective: The patient reported noticeable pain relief, improved mobility, and satisfaction with the ease of treatment and wound healing progress.

Discussion

Leg ulcers in sickle cell disease (SCD) are complex, multifactorial complications that stem from the interplay of vascular dysfunction, chronic hemolysis, local ischemia, oxidative stress, and impaired wound healing. These ulcers are notoriously difficult to treat due to both systemic and localized mechanisms of disease progression. The integrated use of T-AYU-HM Premium and ACUPEN (tablet + ointment) provides a synergistic approach that aligns with various points along this pathophysiological cascade. Allopathic treatments and hematinic supplements were stopped after the first week to allow focused evaluation of the effects of ACUPEN and T-AYU-HM, ensuring the observed improvements could be attributed primarily to these interventions.

Table 2: Follow-up laboratory investigation on 2nd September and 16th November 2024

TEST	2-09-24	16-11-24	Reference /Unit
Hemoglobin (gm/dl)	10.63	8.96	13.5-17.0 gm%
RBC (/cmm)	5.14	4.18	4.6-6.2 mill/cmm
WBC (/cmm)	6740	21000	4000-10000/cmm
Platelet (/cmm)	260000	313000	1.5-4.0 lac/cmm
MCHC (g/dl)	32.11	31.88	32-36 %
MCH (pg)	20.68	21.43	27-31 pg
MCV (fl)	64.39	6.72	80-96 fL
PCV (%)	33.10	28.10	40-54 %
Neutrophil (%)	50	75	55-70 %
Eosinophil (%)	5	7	01-05 %
Basophils (%)	0	0	0-01 %
Lyphocytes (%)	41	15	20-40 %
Monocytes (%)	4	3	02-08 %
ESR (mm/hr)	4	5	< 10Mm/hr
CRP	4.8	7.2	< than 6.00 mg/ dL
Reticulocutes (%)	-	4.9	%
Corrected Reti.Cou	-	3.05	%
Retic.Production Index	-	1.52	%
IRF-Immature Retic. Fraction	-	24.5	%
SGOT	59	-	Upto 40 IU/L
SGPT	73	-	10 - 40 IU/L
Billirubin Total (mg/dl)	4.9	3.0	0.0-1.0 mg/dL
B.Direct (mg/dl)	2.6	1.1	Upto 0.3 mg/dL
B.Indirect (mg/dl)	2.3	1.9	0.1-1.0 mg/dL
Na	-	132.20	135 - 145 mEq/L
Ka	-	4.68	3.5 - 5.5 mEq/L
Cl	-	100.80	96 - 106 mEq/L

Table 3: Comparative clinical observation of leg ulcer progression and healing

Date	Clinical Observation	Ulcer Characteristics	Inflammatory Signs	Healing/ Progress
22-07-2024	Initial presentation	Multiple open ulcers; necrotic base; one with yellow slough and possible pus	Swelling, erythema (redness), signs of acute infection	Active infection, poor perfusion, no signs of healing
02-09-2024	Mid-stage evolution	One ulcer is larger with irregular edges, yellowish-green exudate visible	Still signs of inflammation, hyperpigmentation and some surrounding tissue damage	Partial granulation, infection likely persists
16-11-2024	Recent image	Smaller ulcers, decreased number, some scar tissue; pigmentation around wound	Reduced inflammation, signs of tissue remodeling	**Marked healing** evident, possible post-inflammatory hyperpigmentation

Chronic Hemolysis and Anemia

Pathogenesis: SCD is characterized by persistent intravascular hemolysis, leading to chronic anemia and reduced oxygen delivery to peripheral tissues — especially the lower extremities. This creates a hypoxic environment that promotes ulcer development.

T-AYU-HM Role: *Loha Bhasma* (iron calyx): Supports erythropoiesis and corrects anemia, thus enhancing peripheral oxygen delivery. *Abraka Bhasma* (mica calyx): has a Rasayana (rejuvenative) property, helping restore bone marrow function. Pippali, Guduchi, and Sunthi: Improve hematological parameters and assist in hemoglobin stabilization.(16-19)

Clinical Correlation: Hemoglobin increased from 6.25 → 10.63 g/dL. Reticulocyte indices (4.9%, RPI 1.52) showed enhanced marrow activity.

Increased Oxidative Stress

Pathogenesis: Oxidative stress damages red cells, impairs endothelial integrity, and exacerbates inflammation in the ulcer bed.

T-AYU-HM + ACUPEN Role: Guduchi and Shatavari (from T-AYU-HM): Potent antioxidants that scavenge free radicals and stabilize red cell membranes. *Boerhavia diffusa* and *Triphala* (from ACUPEN): Known for their antioxidant and cytoprotective effects, reducing oxidative burden. Dadima (*Punica granatum*) and Shatavari (*Asparagus racemosus)* possess antioxidant and membrane-stabilizing properties that help reduce the rate of hemolysis, thereby lowering the levels of indirect bilirubin. This hepatoprotective action is reflected in the declining bilirubin levels, indicating reduced red cell breakdown and improved liver function.(16, 19)

Clinical Correlation: Reduction in inflammatory markers (CRP: 31.16 → 4.8 mg/dL). Stabilization of bilirubin suggests decreased hemolysis-related oxidative load.

Cutaneous Vasculopathy and Local Ischemia

Pathogenesis: Endothelial dysfunction and reduced nitric oxide availability impair vasodilation, promoting ischemia and pain. These factors delay wound healing and increase the risk of ulcer recurrence.

ACUPEN Topical and Systemic Role: *Commiphora mukul*, Aloe vera, and *Apium leptophyllum*: Improve microcirculation, reduce inflammation, and promote neovascularization in the ulcer bed. *Ricinus communis*: Known to enhance peripheral blood flow and modulate pain at the site.

Clinical Correlation: Significant wound healing observed between July and November, progressing from active slough to scar formation. Improved dorsiflexion and reduced erythema/induration on physical exam.

Venous Insufficiency, Edema, and Impaired Angiogenesis

Pathogenesis: Post-ulcer inflammation and persistent venous stasis lead to tissue edema and poor angiogenesis, prolonging healing time.

ACUPEN Role: *Triphala*: Known to reduce venous stasis and edema by improving lymphatic drainage. *Boerhavia diffusa*: Anti-inflammatory diuretic properties aid in resolving localized edema.

T-AYU-HM Role: *Jivanti* and *Guduchi*: Support vascular remodeling and tissue regeneration through immunomodulatory and anti-inflammatory actions.

Clinical Correlation: Reduction in local swelling and active pus discharge. Transition to granulation and epithelialization by September.

Genetic and Nutritional Factors

Pathogenesis: Poor nutrition, genetic predisposition, and socio-economic challenges compound the risk of ulceration and poor wound healing.

T-AYU-HM + ACUPEN Role: Shatavari, Haritaki, Sunthi: Act as Rasayana (nutritional rejuvenators), supporting systemic immunity and cellular regeneration. Overall formulation improves nutritional status indirectly through enhanced appetite, digestion, and systemic well-being. (18-21)

Clinical Correlation: Weight stabilization (45.2 kg → 47 kg in early recovery, then 46.8 kg in later phase) indicates improved nutritional uptake and healing status.

Elevated uric acid levels have been linked to the development of leg ulcers in sickle cell disease (SCD), likely due to increased hemolysis, oxidative stress, and vascular dysfunction. A study by Minniti et al. (2011) found that SCD patients with leg ulcers had significantly higher uric acid levels, suggesting it could serve as a marker for ulcer risk. ACUPEN, a polyherbal formulation, contains ingredients like *Boerhavia diffusa* and *Triphala* that help lower uric acid and improve circulation. Its antioxidant and anti-inflammatory properties make it beneficial in managing sickle cell leg ulcers by addressing both systemic and local contributing factors. (16, 22) Several case reports have studied leg ulcer treatment in sickle cell disease (SCD). Posso and Cuellar-Ambrosi (2016) successfully treated a chronic leg ulcer in an 18-year-old female using microsurgical reconstruction. This method needs careful planning and expert surgeons but is costly and not easily available everywhere. Alshurafa et al. (2023) used hyperbaric oxygen therapy (HBOT) to heal a chronic ankle ulcer in an SCD patient. While effective, HBOT is expensive and not widely accessible. (23, 24)

Conclusion

This case report demonstrates that a combined Ayurvedic therapeutic approach using T-AYU-HM Premium and ACUPEN may significantly accelerate the healing of chronic leg ulcers in patients with sickle cell disease. The integrated formulation addressed the root causes of anemia, inflammation, oxidative damage, and vascular compromise—key contributors to non-healing wounds in SCD. Observable improvements in hematological parameters, reduction in inflammatory markers (e.g., CRP), tissue regeneration, and patient functional outcomes reinforce their potential value as adjunct therapies. The present case reinforces the clinically established efficacy of T-AYU-HM in the management of SCD-associated leg ulcers, as supported by prior retrospective and prospective studies. The adjunct use of ACUPEN demonstrated promising complementary benefits in wound healing, meriting further systematic evaluation through controlled clinical trials

Contribution from Authors: AD, KD, HD served as the principal investigators overseeing the case and integrative treatment strategy and patient consent. RD was responsible for monitoring and managing the formulation and documentation. RM contributed to ulcer and joint assessment throughout the

treatment. JD drafted the case report. CD handled clinical observations and contributed to manuscript drafting. All authors reviewed and approved the final manuscript.

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Conflict of Interest: Authors affirm no conflict of interest.

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