

Efficacy of an Ayurvedic Intervention as an Adjunct to Standard Care in Preventing Acute Pain Crises in Sickle Cell Anemia: Protocol of a Randomized Controlled Trial

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Abstract

Background: Sickie Cell Anemia (SCA) represents a major health concern among the tribal population of India, with frequent acute pain crises significantly compromising the quality of life of the affected individuals. As an inherited disorder, there is no definitive cure for the condition. Hydroxyurea remains the primary therapeutic option and is typically used for lifelong management, though it is associated with several side effects. Therefore, considering the urgent need for an accessible, safe, and effective alternative for long-term management of the condition, the present study is planned to evaluate the potential of Ayurveda in managing pain crises in conjunction with conventional standard care.

Objective: The study aims to evaluate the efficacy of Ayurvedic formulations in preventing acute pain crises in SCA and improving the quality of life of affected individuals.

Methods: It is a randomized active, controlled, open-label clinical trial. Patients diagnosed with SCA are enrolled in the study, considering the selection criteria. The study group is administered Ayurvedic interventions such as Dadimadi Ghrita and Ayush-RP along with the standard care, while the control group receives standard care only. The intervention is given for a period of 8 months. Participants are evaluated on the 30th day, 60th day, 105th day, 150th day, 195th day and 240th day to assess changes in pain crisis frequency, haemoglobin levels, and quality of life improvements.

Results: The study has been initiated on 5th September 2023. Out of the total 1518 screened participants, 1371 enrolled, 791 participants have successfully completed, 498 participants are continuing while 82 participants dropped out from the study as of 22nd January 2025.

Conclusions: The study is expected to demonstrate the efficacy and safety of Ayurvedic interventions as an integrated approach in managing SCA by reduction in the frequency of pain crises, aiming to improve the overall quality of life for the patients. Clinical Trial: CTRI/2023/04/052141

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Original Manuscript

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Abstract

Background: Sickle Cell Anemia (SCA) represents a major health concern among the tribal population of India, with frequent acute pain crises significantly compromising the quality of life of the affected individuals. As an inherited disorder, there is no definitive cure for the condition. Hydroxyurea remains the primary therapeutic option and is typically used for lifelong management, though it is associated with several side effects. Therefore, considering the urgent need for an accessible, safe, and effective alternative for long-term management of the condition, the present study is planned to evaluate the potential of Ayurveda in managing pain crises in conjunction with conventional standard care.

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Conclusions: The study is expected to demonstrate the efficacy and safety of Ayurvedic interventions as an integrated approach in managing SCA by reduction in the frequency of pain crises, aiming to improve the overall quality of life for the patients.

Keywords: Sick Cell Anemia, Pain Crises, Hemoglobin, *Raktavaha srotas dushti*; *Dadimadi Ghrita*, Ayush-RP

Trial registration number: CTRI/2023/04/052141

Introduction

Sickle cell anemia (SCA) is a hereditary condition within the broader group of sickle cell diseases (SCD). It is one of the most prevalent monogenic disorders globally and is particularly common among the tribal populations in India.ⁱⁱⁱ SCA is a disease caused by a mutation in the β -globin gene, leading to the production of abnormal hemoglobin, which binds with other abnormal hemoglobin molecules within the red blood cell (RBCs) to cause rigid deformation of the cell. The abnormally shaped RBCs are unable to pass through the small vascular channels, resulting in sludging and congestion within the vascular beds, tissue ischemia and infarction. The frequent occurrence of infarction in individuals with SCA is a principal cause of the early clinical manifestation, the acute pain crisis, often ascribed to bone marrow infarction.ⁱⁱⁱ The vaso-occlusive pain episodes frequently affect the limbs, abdomen, ribs, sternum, spine, and occasionally the skull, often elicited by illness and accompanied by clinical features as fatigue, loss of appetite, anemia, jaundice, pneumonia, and recurrent infections. The life expectancy for those with SCA ranges from 42 to 48 years, with 50% of affected children dying before age 5, primarily due to recurring infections.^{iv}

Due to the genetic predisposition, the sickle cell gene is found amongst different tribal groups of India varying from 5 to 34 %, according to an ICMR survey.^v Maharashtra is one of the states in India with a high prevalence of SCA, where Vidarbha region demonstrates a significantly higher prevalence, with 62% of the total cases concentrated in the Nagpur division. This is significant

considering there are approximately 2.10 lakh carriers in the region.^{vi}

Hydroxyurea, a ribonuclease reductase inhibitor, is the drug of choice in the management of SCD and has demonstrated reduction in painful episodes, acute chest syndrome, as well as mortality. However, it is an extremely toxic drug^{vii} and requires intensive monitoring to prevent side effects as neutropenia, bone marrow suppression, elevation of hepatic enzymes, anorexia, nausea, vomiting and infertility.^{viii} Blood transfusion is crucial in managing complications like acute chest syndrome, heart failure, stroke, and aplastic crises, although it possesses risks such as iron overload and viral transmission, requiring vigilant oversight.^{ix} Preventive care includes genetic counseling, neonatal screenings, parental education, immunizations, prophylactic antibiotics, proper nutrition, hydration, etc. All of these are multidisciplinary approaches and require a significant amount of teamwork.^x In SCA, acute pain requires opioids and hydration, and chronic pain is associated with debilitating conditions. One of the impediments to effective pain management is the inability of healthcare providers to accurately identify the cause of the pain due to misperceptions and fear of opioid addiction, due to which the pain management is highly challenging.^{xi}

While there is no permanent cure for SCA, the severity can be reduced by adequate management, improving the quality of life of the affected individuals. As the disease requires lifelong therapy and exerts a considerable macroeconomic impact on the economy due to the severe complications, newer alternatives must be evaluated to establish an effective and safe long-term management. In Ayurveda, hereditary diseases are classified as *Adibalapravritta Vyadhi*, which refers to disorders originating from the impairment of the sperm and/or ovum. These conditions are attributed to genetic imbalances inherited from both parents. While such conditions are considered *Asadhya* (incurable) in Ayurvedic texts, the principles of Ayurveda, combined with modern medicine, can assist in the reduction of painful crises and improve outcomes.^{xii} Therefore, the present study is planned with an aim to significantly improve the quality of life for those affected by the impactful integrated approach of Ayurveda interventions and provide more alternatives for better outcomes in the management of the disease.

Objectives

The primary objective of the study is to evaluate the therapeutic efficacy of *Ayurvedic* formulations as add-on to standard care for the prevention of acute pain crises in SCA. Secondary objectives comprise the evaluation of the safety of the Ayurvedic formulation, the assessment of its effect on different pathological and biochemical parameters, and the quality of life of patients with SCA.

Methodology

Study Design

This is a randomised, active, controlled, open-label clinical trial.

Study Setting

The study is being conducted at three centers - Civil Hospital in Gadchiroli District, Acharya Vinoba Bhave Rural Hospital (AVBR) Hospital in Sawangi (Meghe), Wardha District, and Shalinitai Meghe Hospital & Research Center in Wanadongri, Nagpur, Maharashtra, India. The participants are screened from all three centres while the enrolment takes place at the latter two institutes.

Inclusion Criteria

Participants aged 18 to 50 years of any gender, diagnosed with SCA confirmed by haemoglobin electrophoresis showing the HbSS pattern are eligible for the study. They should meet the following laboratory criteria: Hemoglobin > 6 gm%, Platelets > 100,000/cu.mm, Serum Creatinine $\leq$ 1.5 mg/dl, International Normalized Ratio (INR) $\leq$ 2.0, and partial thromboplastin time $\leq$ 48 seconds. Additionally, participants should be willing to adhere to the study procedures and follow-up schedule and provide written informed consent.

Exclusion Criteria

Individuals are excluded from the study if they have a history of five or more hospitalizations for pain in the past 12 months; require transfusions more frequently than once every three months; have a history of bleeding diathesis or a clinically overt stroke within the past two years; are receiving chronic anticoagulation or anti-platelet therapy; or have previously undergone a hematopoietic stem cell or solid organ transplant, recent RBC transfusion (within 60 days); a history of cardiac arrhythmia, acute coronary syndrome, myocardial infarction, or stroke; or symptomatic congestive heart failure. Individuals with chronic liver disease, alanine transaminase/ aspartate transaminase levels exceeding three times the upper limit of normal, hypertension (blood pressure $\geq$ 160/100 mmHg), or clinically significant infections are also excluded. Further, those unable to take oral medications or with malabsorption syndrome, active substance abuse, renal dysfunction (serum creatinine > 1.5 mg/dL for males or > 1.1 mg/dL for females), uncontrolled pulmonary dysfunction (asthma, chronic obstructive pulmonary disease), or other severe comorbidities are excluded. Individuals with clinical manifestations as hepatitis, glycated haemoglobin (HbA1C) $\geq$ 8, Acquired immunodeficiency syndrome/ human immunodeficiency virus, malignancy, hyperthyroidism, or current participation in another clinical trial are also ineligible. Women planning conception, pregnant, or lactating are excluded, as well as individuals with conditions that the principal investigator deems may pose a risk to study safety or integrity. In addition, those with heterozygous sickle cell trait (AS pattern) or a history of severe sickle cell crises are excluded.

Rationale for Selection Criteria

The age group 18-50 is selected for improvement in the health and quality of life for SCA patients. Above 50 years the incidence of SCA is likely very minimal and induce variations & confounders because of co-morbidities. The maximum life expectancy of SCA patients noted earlier is 47 years.^{xiii}

Withdrawal criteria

Withdrawal from the study may occur if the participant chooses to leave, if their condition deteriorates, or if they develop any health conditions listed in the exclusion criteria during the study. Participants who withdraw undergo a final examination, if possible. In cases where a participant leaves against medical advice, a final telephone interview is conducted to assess their health status. The reasons for withdrawal are documented in the case record form.

Study Procedure

The participants diagnosed with SCA are enrolled based on the selection criteria from the respective outpatient departments of the screening centers. The duration for the intervention is 8 months for each participant, comprising visits on the 30th day, 60th day, 105th day, 150th day, 195th day and 240th day. Participants are evaluated for demographic details and medical history on the baseline and are provided the study drugs at each subsequent visit. During this period, participants are being assessed for primary and secondary outcomes. The scheduled haematological (CBC, ESR, BT, CT, and PT/INR, Free haptoglobin, Peripheral smear, complete electrophoresis) & biochemical investigations (Fasting blood sugar levels, HbA1C, Liver function test, Renal function test, C-Reactive Protein) and urine routine investigations are conducted at baseline, on the 60th day, 150th day, and 240th day. Radiological investigations (ECG & USG) are conducted at baseline and 240th day. For every visit, the window period is 7 days to the respective date of visit to minimize dropout due to unavoidable circumstances. The participants are instructed to immediately inform if they encounter any adverse reaction throughout the study.

Interventions

Participants in both groups receive standard care, which includes tablet Folic acid 400 mcg once daily after meals and tablet Hydroxyurea 500 mcg once daily after meals, in accordance with operational guidelines for the management of SCA.^{xiv} In addition to standard care, participants in the study group are administered *Dadimadi Ghrita*^{xv} at a dosage of 12 gm twice daily before meals with lukewarm water, and tablet Ayush RP at a dosage of 500 mg twice daily after meals with lukewarm water. Each medication is administered orally for a duration of eight months.

The study drug *Dadimadi ghrita* is purchased from Good Manufacturing Practices certified

company-Indian Medicines Pharmaceutical Corporation Limited, Mohan, Almora, Uttarakhand, India. The other drug, Ayush-RP is procured from the Central Ayurveda Research Institute's Ayurveda Pharmacy, Jhansi, Uttar Pradesh, India. The formulations are prepared in accordance with the specifications outlined in the Ayurvedic Formulary of India. The quality control parameters of the raw drugs used in the formulations have been verified to comply with the limits specified in the Ayurvedic Pharmacopeia of India (API). The safety parameters of *Dadimadi Ghrita* have been validated as per API standards.

Drug compliance

The drug compliance forms are issued to the enrolled participants on each visit. The participants with equal to or more than 80% compliance continue in the study. The compliance is assessed at every visit by evaluating the approximate quantity of study intervention consumed by the participants and the returned containers of medicines.

Concomitant and Rescue medication

The participants are instructed not to take medicines other than the study drugs for any disease without consulting the investigators. The concomitant therapy is continued for diabetes mellitus & hypertension or any other disease that has not been specifically mentioned in the exclusion criteria. The investigators may prescribe any concomitant medications or treatments deemed necessary to provide adequate supportive care during the intervention period. The name, indication, dose, unit, frequency, start date, and stop date (if applicable) for all interventions are recorded on each participant's Case Record Form (CRF). Administration of any rescue medicines in case of any medical emergency is documented in the CRF. The Investigator instructed the participants to consult them for any other signs and symptoms or if anything unusual occurred.

Outcome Measures

The primary outcome of the study is the incidence or frequency of sickle cell-related pain crises, defined as the onset or worsening of pain lasting at least 2 hours, with no cause other than vaso-occlusion, requiring treatment with opioids, non-steroidal anti-inflammatory drugs, or other analgesics prescribed by a healthcare provider in a medical setting (hospital, clinic, emergency room, or at home).

Secondary outcomes include changes in haemoglobin levels, lactate dehydrogenase, reduction in the frequency of bleeding episodes, RBC transfusions, and hospital admissions due to pain during the treatment period; improvement in haematological parameters (CBC, HbS, HbF, HbA), Intensity of pain measured by Visual analog scale (VAS) score, hospital stay duration,

incidence and severity of adverse event (AE), analgesic/opioid use, and changes in indirect bilirubin, potassium, free haptoglobin, and inflammatory markers (CRP). The study also assesses fatigue using the Modified Fatigue Impact Scale (MFIS) score and quality of life through the 12-Item Short Form Health Survey (SF-12 scale).

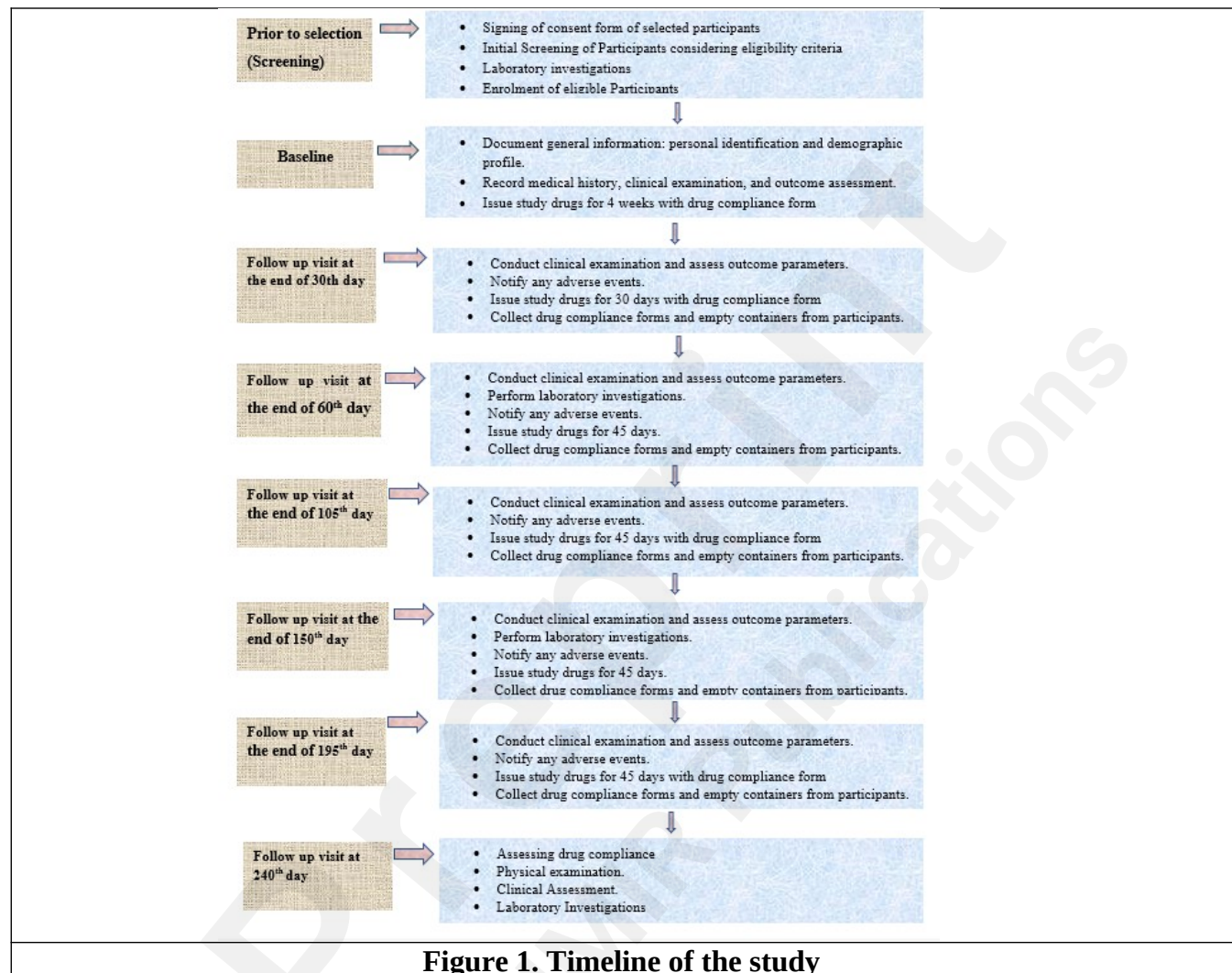


Figure 1. Timeline of the study

Safety outcomes

The safety of the study intervention is evaluated by recording the incidence of AE on every scheduled visit. All AEs during the study timeline, if they occur, are recorded and monitored as per the Good Clinical Practice guidelines. The safety assessment is done through hematological and biochemical investigations, as mentioned.

Sample size

The inputs used for the sample size calculation are: $Z\alpha = 1.64$, $Z\beta = 0.84$, and the true proportion difference between two groups in the sickle cell population (Difference in Proportion ϵ) = 5% = 0.05. For superiority testing, the clinically acceptable effect size (δ) for a single-tailed test is 11.5% = 0.115. The expected proportions are $P1 = 35\% = 0.35$ and $P2 = 40\% = 0.40$.

Based on these inputs, the sample size per group is calculated to be 685, making the total sample size 1370. Accounting for a 10% dropout rate, the final sample size required is approximately 1510, with 755 participants needed per group.

Randomization and allocation

Participants are randomly assigned to either the interventional or control group in a ratio of 1:1, according to a pre-specified randomization scheme prepared by using a computerized system. To prevent selection bias, the randomization sequence is concealed using the sequentially numbered, opaque, sealed envelope (SNOSE) method. Following the baseline assessment, an envelope enclosed with the slip containing the details of the allocated group is opened by the participants in front of the investigator. The participants are then assigned to the designated groups.

Data collection

All data related to the study is properly documented in both the CRF and electronic format. Investigators and project staff at the participating centers have received training to ensure standardized data collection procedures. All source documentation supporting the entries in the CRFs is maintained and kept readily accessible. These documents are securely stored at the study centers. The records and data collected during the study are stored in password-protected folders on secure computers and external storage devices, with only access restricted to the Investigator.

Statistical analysis plan

The statistical analysis will be conducted after data collection, with a verification of its accuracy and limitations. Categorical variables will be presented as numbers and percentages, and pre-post-trial comparisons will be analyzed using the McNemar Chi-Square Test/Cochran's Q test. Continuous variables, such as scores and laboratory parameters, will be assessed using the paired/unpaired t-test, if the data follows a normal distribution, or the Wilcoxon test if the data is non-normally distributed. For analysis of assessment parameters across multiple follow-ups, the repeated measures will be analyzed using r-ANOVA for normally distributed data, or the Friedman test/Cochran's Q test for non-normally distributed or categorical data. Data with a normal distribution will be reported as mean $\pm$ standard deviation (SD), and non-normally distributed data will be presented as median with interquartile range (Q1, Q3). A 5% level of significance ($p < 0.05$) will be applied throughout the analysis, and SPSS version 29.0 software will be used to perform all statistical tests.

Data monitoring

The interim analysis will be done on completion of the intervention period of at least 25% of participants. The Committee for monitoring the study systematically evaluates the progress of the study through scheduled review meetings and site visits, as required, to ensure rigorous adherence to the study protocol, as well as the completeness, accuracy, and consistency of the data. Additionally, the Committee ensures compliance with relevant local regulations pertaining to the conduct of clinical research.

Study drug management and accountability

The study drugs are securely stored under the observation and responsibility of the investigators. A meticulous record of the dispensed study drugs is maintained to prevent any discrepancies between the quantity dispensed and the amount remaining or returned.

Ethical Considerations

The study is conducted in accordance with ethical principles as per the Declaration of Helsinki for biomedical research and the Indian Council of Medical Research ethical guidelines involving human participants (2006), which are consistent with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's guideline for Good Clinical Practice guidelines.^{xvi} The recruitment started after obtaining approval from the Institutional Ethics Committee and registration in the Clinical Trials Registry- India (Trial registration number: CTRI/2023/04/052141).

Protocol amendment

Any deviations from the study protocol will be executed after prior approval from the Institutional Ethics Committee.

Informed Consent

Written informed consent is obtained from all participants, along with the provisions of benefits and limitations of the study, which are clearly outlined in the consent forms and explained to participants prior to the commencement of the study.

Confidentiality

All participant information, including laboratory results, are securely stored. Blood samples and study records are identified by a unique Base ID. Documents with personal identifying information are reserved separately in a secure location. In addition to the study team, authorized personnel have access to participant records to monitor the study.

Result:

The study has been initiated on 5th September 2023. Out of the total 1518 screened participants, 1371 (686 in interventional group and 685 in control group) have been enrolled in the

study. 791 participants have successfully completed, 498 participants are continuing while 82 participants dropped out (43 in interventional group and 39 in control group) from the study, as on 22nd January 2025.

Discussion

In Ayurveda, disease management focuses on understanding the pathogenesis of the condition. SCA can be explained in terms of *Raktavaha Srotas Dushti*, which refers to the imbalance or dysfunction of the hematopoietic system. In some studies, it has been correlated with *Sannipataja Pandu Roga*.^{xvii,xviii} The *Yakrita* (Liver), *Pleeha* (Spleen) and *Amashaya* (Stomach) are the sites involved in transformation of the *Rasa* (essence of the digestive food elements) into *Rakta* (Blood) with the help of *Ranjaka Pitta*^{xix} (intrinsic factor responsible for erythropoiesis), a predominant factor for the formation of *Rakta*.^{xx} The *Beejadushti*^{xxi} (Genetic mutation) may cause altered development and functioning of *Raktavaha srotas* as well as *Ranjaka Pitta*, which hampers the formation of *Rakta Dhatu* (blood tissues). The depletion is accompanied by imbalances in other *Dhatus*, aggravating *Vata Dosha* (body humour)^{xxii}. The clinical features of *Raktavaha srotas dushti* comprises *Jeerna Jwara* (Chronic fever) *Yakritodara* (Hepatomegaly), *Plihodara* (Splenomegaly) etc.^{xxiii} The pathology in *Raktavaha srotas* can lead to several diseases, including *Raktapitta*^{xxiv} (Bleeding disorder) which may be associated with sickle cell disease. It subsequently results in complications such as *Raktakshaya* (deficiency of blood), identified by *Sirashaithilya* (deformity of blood vessels), and manifestations in the appearance of skin^{xxv}.

In the SCA, the pathogenesis lies in the hemoglobinopathy, which causes the sickling of RBCs. Due to increased oxidative stress and production of reactive oxygen species^{xxvi}, it further leads to endothelial dysfunction, cell adhesion, vaso-occlusion and hemolysis. The resultant tissue ischemia and infarction is responsible for the acute systemic painful vaso-occlusive crisis^{xxvii} and anemia, as the extent of compensatory increased RBCs production is insufficient to balance its increased rate of destruction.^{xxviii} Consequently, it affects the systemic organs as liver, spleen, kidneys & lungs and causes neurological, cardiovascular, renal and urological complications.^{xxix}

There are various drugs illustrated in Ayurveda for the management of *Raktadushti* (Vitiation of blood), among which *Dadimadi ghrta* is selected in the present study due to its *Rakta vardhana* (increases blood), *Balavardhaka* (increases strength) action. The formulation is based on ghee, which itself have properties like *Brumhana* (nourishing or promoting growth) and *Pushtikara* (providing strength or vitality) aiding in pacifying *Vata dosha*^{xxx} It contains potent ingredients like *Chitraka* (*Plumbago zeylanica*), *Dhanyaka* (*Coriandrum sativum*), *Shunthi* (*Zingiber officinale*), and *Pippali* (*Piper longum*), which are known for their digestive and detoxifying properties. These ingredients

support *Deepana*, enhancing the digestive process, and *Pachana*, with *Pippali* and *Chitraka* helping to detoxify the body by eliminating Ama (undigested waste products). The combination promotes proper nutrition for all *Dhatu* (bodily tissues) and contributes to *Dhatuposhana* (nourishment of tissues) by improving digestion, reducing the accumulation of deranged doshas, and boosting metabolism. Furthermore, the antioxidant properties *Dadima* (*Punica granatum*), *Dhanyaka*, and *Shunthi* possess help in the reduction of oxidative stress, particularly in sickle cell conditions, and may assist in managing and preventing complications associated with SCA.^{xxxii}

The other interventional drug, *Ayush RP*, is a coded drug developed by the Central Council for Research in Ayurvedic Sciences (CCRAS). According to a pilot study conducted previously on different tribal population residing in Maharashtra, the formulation *Ayush RP* showed significant improvements in reducing pain crisis episodes and enhancing the quality of life for participants diagnosed with SCA.^{xxxiii} The ingredients have *Raktaprasadan karma*^{xxxiii}, an action that improves blood quality by restoring balance to the dysregulated *Pitta dosha*, eliminating vitiated factors, and modulating the components of the blood. This may help alleviate the *Raktadushti* and further facilitate the free circulation of blood. The action of the constituents such as *Lekhana karma* (scrapping of unwanted tissues) helps in the elimination of the *Sanga-srotodushti* (Obstruction in minute channels of the tissues). Consequently, it may reduce vaso-occlusion and further mitigate painful crises. Additionally, the *Shonitasthapana* action may regulate hemolysis and enhance blood volume. *Ruksha*, *Sheeta Guna*, *Tikta-Kashaya Rasa*, *Madhura Vipaka*, and *Sheeta Veerya* of the formulation pacify *Tridosha* (all three body humors) and *Raktadushti*, and its ingredients are particularly mentioned in Ayurveda texts for managing *Rakta Vikara* (Blood disorders), specifically *Raktapitta*. Also, the components support *Dhatuposhana*, which may improve the overall strength and vitality of the body. The formulation comprises nano-active particles that increase the bioavailability of the compound, assisting in better absorption and assimilation. The ingredient of the formulation possesses anti-pyretic, analgesic, anti-inflammatory, immunomodulatory, antioxidant, antimicrobial, hepatoprotective properties and is considered to elevate the serum iron levels as per pharmacognostical, pre-clinical and clinical studies.

Hydroxyurea is the primary drug in the management of SCA and is currently the most effective disease-modifying therapy for individuals with SCA,^{xxxiv} which reduces the production of rapidly dividing cells, including those involved in the inflammatory processes in sickle cell disease. It increases the production of fetal hemoglobin (HbF), which helps to reduce sickling of red blood cells and the frequency of painful episodes. It also increases overall hemoglobin levels, improving oxygen delivery and reducing the severity of symptoms.^{xxxv} Also, there is often increased

erythropoiesis as the body attempts to compensate for the rapid turnover of sickled red blood cells. This heightened demand for new RBCs places a greater need for folic acid, a crucial vitamin involved in DNA synthesis and cell division. For this reason, Folic acid is prophylactically recommended in the standard treatment care.^{xxxvi}

Overall, these interventions as an integrated approach are expected to enhance bioavailability of the drugs at cellular level, eliminate vaso-occlusion, reduce oxidative stress, inflammatory conditions, hemolysis, organ damage, as well as frequent episodes of pain crises and the requirement of blood transfusion, ultimately improving the quality of life for individuals affected by the disease.

Strengths and limitations

The strength of the present study is the robust study design as Randomized active controlled trial (RCT). Along with this, the innovative approach of the study, as the integration of the standard and Ayurvedic interventions in the management of SCA, may enhance the therapeutic outcomes due to the potential synergistic effects of the holistic management. However, the evaluation of the specific impact of Ayurvedic interventions is challenging as the integrated approach may present a limitation in the assessment of the independent effectiveness of the intervention.

Future scope

A future RCT could be designed to compare the efficacy of Ayurvedic interventions versus the standard therapeutic care in the management of SCA, facilitating a precise evaluation of the effectiveness of each approach.

Conclusion

SCA, being a hereditary condition, is currently devoid of a definitive treatment in both conventional and traditional methods and is instead prevented and managed symptomatically. The present study is designed with an integrated approach, aiming to enhance the quality of life for SCA patients by effectively managing and preventing the occurrence of severe painful vaso-occlusive crises.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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