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Research Article

REAL-WORLD EXPERIENCE OF HEMOXIN R PLUS (NIKOSAN K PLUS): RETROSPECTIVE ANALYSIS ON 150 PATIENTS

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ABSTRACT

Sickle cell disease (SCD) is amongst the most common genetic hematological disorders. Hand-foot syndrome (swelling), pain and anemia are some of the very common complications of the disease. In Sickle cell anemia, the number of healthy RBCs decrease which results in reduction of oxygen in the tissues. Majority of the SCD patients are from low socio-economic strata and can barely afford costly treatment modalities. Retrospective analysis was done on 150 patients who consumed a proprietary Ayurvedic medicine, Hemoxin R Plus (Nikosan K Plus). **Objectives:** Sickle cell anemia impacts quality of life of patients which include pains including joint pain, abdominal pain, and total body pain. It also leads to breathlessness, weakness or fatigue and hence difficulties in doing daily chores. Our aim was to evaluate safety and efficacy of Hemoxin R Plus, an Ayurvedic medicine in improving quality of life in patients having SCA. **Materials and Methods:** This was a retrospective analysis. Hospital records of the patients were used and reviewed for the analysis. The doctors who treated the patients collected the data from the medical records department. Wilcoxon signed rank test was applied for analysis. Parameters related to the quality of life were studied. The parameters considered were pain (whole body, abdominal, limbs/joints, back), fatigue, breathlessness, difficulty in doing daily activities and absenteeism (school/job). **Results:** For every parameter considered for analysis, the probability value (*p value*) was found to be <0.05, confirming the statistical significance in reduction of symptoms. Hemoxin R Plus was found to be safe in the dose administered, as there were no adverse events reported. **Conclusion:** Capsule Hemoxin R Plus can be used for of the management of sickle cell anemia in pain reduction and in improving the quality of life.

INTRODUCTION

Sickle Cell Anaemia (SCA) is the most common and severe form of SCD. It is most prevalent in malarial endemic areas in the tropics where outcomes are generally not that good because of the limited resources. Most children die before reaching the adulthood because of these reasons.

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In 2006, the WHO has considered SCA as a public health priority and subsequently adopted a resolution on the prevention and management of birth defects, including sickle cell disease and thalassemia at the 63rd (2010) World Health Assembly.[1]

Normal RBCs are round shaped which can flow through blood vessels and capillaries easily. As the name suggests, in sickle cell anemia RBCs become sickle shaped and rigid. As the morphology of the cells changes, the RBCs tend to get stuck in the smaller blood vessels, hampering the blood and, in turn oxygen supply to the body. James Herrick[2] first recognized SCD in the year 1910. Sickle hemoglobin was firstly illustrated in India by Lehman and Cutbush in the year

1952 in south India[3]. In India, prevalence of sickle gene is found to be 0-18% in northeastern part, 0-33.5% in western part, 22.5-44.4% in central part. The prevalence of SCD diverges substantially amongst various tribal groups, and it ranges from 0 to as high as 35%. In states like Maharashtra, MP, Gujarat, Orissa, Chattisgarh, Jharkhand, it is a major public health concern. It is prevalent more amongst the tribal groups and in the people from scheduled caste[4].

HBB gene mutates to create Sickle hemoglobin[5]. Inheritance is recessive here in this case. Individuals with single globin chain defect are called as carriers or traits or heterozygotes. Carriers are generally symptomless. Sickle cell anemia is caused if the gene for sickle hemoglobin is inherited from both the parents.

There is no proper mentioning of Sickle Cell Anemia as such in Ayurveda but the disease resembles with (one of the subtypes of) *Panduroga*[6]. In *Panduroga* there is depletion of blood, due to which, complexion becomes pale; and there are symptoms such as irritability, fatigue etc. The cause of *Panduroga* is the depletion of *Rasa* and *Rakta Dhatu* with other *Dhatus* and vitiation of *Tridosha*[7].

The term *Beejadosha* is parallel to the 'genetic defects or abnormalities'. Symptoms associated with Sickle Cell Anemia are, difficulty in breathing, fatigue, pain etc. Essence of the *Dhatus* (the tissue proper) is called *Ojas.* One canzinfer that in SCA, there is a depletion of *Ojas,* resulting in various debilitating symptoms and early death.

The difficulties associated with this disease are known to have serious negative impacts on the overall Quality of Life (QoL) of affected individuals. Therapies for sickle cell anemia are aimed to avoid/reduce pain and preventing complications. Treatments available include medications, blood transfusions and at times, bone-marrow transplant. Other strategies include hypnosis, some exercises, meditation etc. Acupuncture and yoga can also be used as pain therapies. As the disease cannot be cured *per se*, with the oral medicines, this needs treatment which can maintain the quality of life of patients[8].

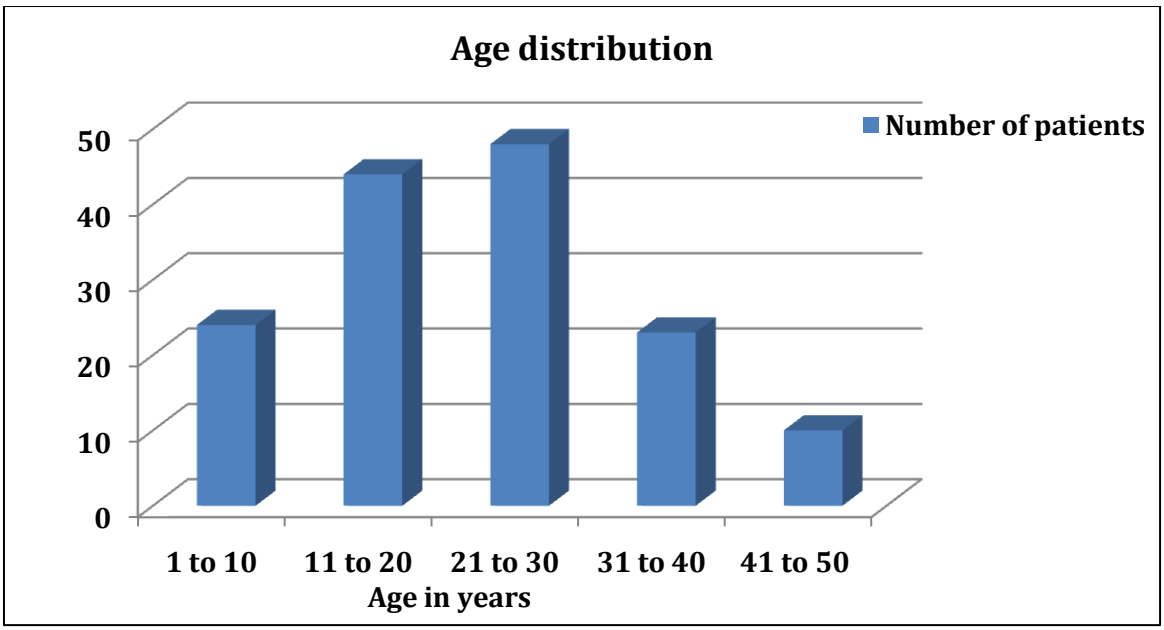
Ayurved medicine found to be effective in managing symptoms of Sickle Cell Anemia, in this retrospective analysis drug was Hemoxin R Plus. The assessments were based on pain of various types and few parameters of Quality of Life.

MATERIALS AND METHODS

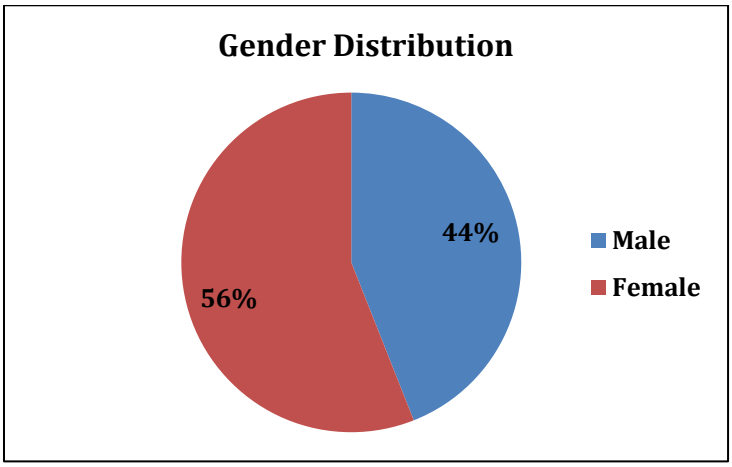
Study Population

Data of 150 Sickle Cell anemia patients with complaints like abdominal pain, joint pain, back pain, total body pain, fatigue, breathlessness, difficulties in doing daily chores, attending school/job collected retrospectively by the investigators and their assistants from Tapivan Gramin Vikas Charitable Trust, Surat. All the patients in the study were of Sickle Cell Disease, diagnosed for more than a year and were on medication like Folic acid and/or a few on Hydroxyurea. Patients were having at least one or more symptoms/complaints described above.

Demographic information, family history and personal history were noted. Patients were of age from 4 years to 48 years.



From 150 patients 84 were female and 66 were male.



(a) Medication Used: Capsule Hemoxin R Plus (A proprietary Ayurvedic medicine)

Each capsule contains,

- *Sarjika Kshar* (Sodium Bicarbonate and Sodium Carbonate): 200mg
- *Lavang* (*Syzygium aromaticum*): 28mg
- *Vijaysar* (*Pterocarpus marsupium*): 40mg
- *Maricha* (*Piper nigrum*): 36mg
- *Jawar* (*Sorghum vulgare*): 76mg
- Papaya (*Carica papaya*): 120mg

  Plus excipients

Dose: For adults: 500mg capsule once a day; Children: 1/2 capsule of 500mg once a day.

Investigations

Following symptoms were observed before and after treatment

S. No		Symptoms/ Complaints
1.	Pain	Abdominal pain
2.		Limb/ Joint pain
3.		Back pain
4.		Overall body pain
5.	QoL	Fatigue
6.		Breathlessness
7.		Difficulty in performing daily chores (activities of daily life: ADL)
8.		Difficulty in attending school/job

Grading was done on the basis of severity for above parameters (0- No symptom and 10- Worst possible case)

Demographic and clinical data was collected from the trust. Grading was done for the above complaints for before and after status of giving Hemoxin R Plus for an average duration of around 2 months. Improvement in pain and Quality of Life of patients were the outcomes of the study.

RESULTS AND DISCUSSION

Clinical condition of patients with Sickle Cell Anemia worsens day by day if proper treatment is not given. In this study, the patients were on a particular Ayurvedic drug called Hemoxin R Plus to minimize the symptoms and to improve Quality of Life.

Pain (general body ache, limb and joints pain, abdominal pain and back pain) and four parameters that represent QoL viz. fatigue, breathlessness, difficulty in carrying out Activities of Daily Living (ADL) and difficulty in attending job / school were assessed. Ordinal scale (0 for best scenario/no symptom and 10 for worst case scenario) was considered for every parameter.

Wilcoxon signed rank test was used to analyze the before-after data

	Body pain	Limbs/ joints pain	Abdomen pain	Back pain	Weakness	Breathlessness	ADL	Attend Job/school
Negative Ranks	34	140	67	127	127	53	141	104
Positive Ranks	1	0	2	0	0	1	0	0
Ties	115	10	81	23	23	96	9	46
Total	150	150	150	150	150	150	150	150
Test statistic	-5.206	-10.342	-6.782	-9.855	-9.698	-6.389	-10.422	-8.95
P value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Interpretation: Negative rank indicates a decrease after the treatment for each parameter. Positive rank indicates increase after the treatment, while a tie indicates it to remain same.

For every parameter analyzed, p value was found to be <0.05, defining there was significant difference after treatment. In some of the patients, complaints like body pain, abdominal pain, back pain, fatigue and breathlessness were absent before treatment. In remaining almost all the patients the grades got reduced and treatment was found to be effective. For limb/joint pain, ADL and attending school/job, almost all patients showed reduction in grading which indicates treatment is effective across all patients.

Complaints in the SCA mainly affect Quality of Life (QoL) hence it was important to assess effect of the Hemoxin R Plus in improving quality of life of patients. Assessment for Quality of Life (QoL) was done before and also after treatment. Scores were compared for assessing improvement/change. SCD patients in general have a bad health related quality of life as compared to the general population[9]. Quality of life of SCD patients is as severely compromised, hence reducing mortality is of paramount importance among SCD patients, future interventions should consider improving health related quality of life as a clinical endpoint[10]

Pain is the most common complication associated with the patients having SCD. It could be daily chronic pain as well as intermittent. When the sickle cells get stuck in smaller blood vessels and capillaries, they clog the blood flow to the chest, abdomen and joints. This phenomenon causes pain that may start suddenly; it can range from mild to severe, and can last for a varied length of time[11]. There are unpredictable acute vaso-occlusive painful episodes called pain crises. These pain episodes often require emergency acute medical care. Due to unpredictability and subjective and varied nature of pain, managing pain crises is a challenge for both, patients and their healthcare providers. Based on experience and on various studies it was crucial to include this as a clinical endpoint[12]. In a particular study it was found that pain episodes include pain in legs, back and abdomen. Patients with sickle cell anemia, has a negative impact on the emotional, physical and occupational aspects of life. A study found that a higher percentage of Sickle Cell Anemia patients were unemployed compared to the other population[13]. Attending jobs get difficult with Sickle Cell Anemia due to health complaints. In another study it was noted that sickle cell pain resulted in over seven times increased risk of absenteeism from school[14]. Hence in the present study we considered school/jobs absenteeism as one of the factors under QoL assessment.

As discussed above the important factor in physiology of Sickle Cell Anemia is reduced amount of oxygen throughout body which affects the respiration rate and causes fatigue. Hence breathlessness and weakness were considered while evaluating the patients. A study in Curitiba showed that Sickle Cell Disease interferes with daily lives of patients, 62.5% physically with a potential limiting factor.[15]

All the parameters considered to assess efficacy thus were carefully chosen to understand the overall effect of Hemoxin R Plus in managing SCA. All the parameters were closely monitored during the medicine was being administered, as each of them was critical to assess clinical significance of Hemoxin R Plus. No patient exhibited any symptom of adverse drug reaction, and it seemed to be extremely safe. The individual contents of the drug have good safety profile, and most of the contents are used as 'food' too.

Through these clinical benefits achieved, especially in fatigue and breathlessness, one could hypothesize that there is an increase in the hemoglobin level. However, current study lacks this direct evidence, as the very analysis is retrospective, and systematic laboratory investigations were not done.

CONCLUSION

This was the retrospective analysis of the patients of sickle cell anemia treated with Hemoxin R Plus. The study concludes that after giving Hemoxin R

Plus the patients of sickle cell anemia showed relief from pain in limbs, abdomen, back and body. Reduction in pain helped in doing activities of daily living and attending school/job (less absenteeism). The drug also showed significant relief in fatigue and breathlessness, indicating that there could be an increase in the hemoglobin level too. The drug was tolerated very well without any known adverse reaction, exhibiting safety of this Ayurvedic drug.

Limitations

Our study shows that Hemoxin R Plus is safe and effective in treating SCA patients. However, this was retrospective study and the data was limited to clinical outcomes only. A larger, prospective trial in the future with Hemoglobin gm% as one of the parameters, will shed more light on the clinical as well as laboratory outcomes.

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