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Amalaki rasayana and max HB in sickle cell anaemia: An open label non-comparative clinical trial

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Abstract:
Sickle cell anaemia is an inherited hemoglobin disorder characterized by sickling of red blood cells, leading to vaso-occlusion, chronic anaemia and recurrent systemic complications. Therefore, it is of interest to evaluate the clinical efficacy of *Amalaki Rasayana* and Capsule Max HB in the management of sickle cell anaemia. An open-label, non-comparative clinical trial was conducted on 25 patients at Government Ayurveda College and Hospital, Bilaspur, Chhattisgarh, with outcomes assessed over 60 days using the Dutch-AIMS2-HFF Symptoms Severity Scale, Wilcoxon Signed Rank Test and paired t-test. Treatment produced significant improvements in subjective symptoms, including anaemia (35.71%), pallor (43.40%), bodyache (37.50%), palpitation (43.86%), hand-foot syndrome (25.58%), loss of appetite (41.18%) and recurrent respiratory infection (37.78%), with an overall improvement of 37.86%, alongside increases in Hb, RBC, MCH, MCV and MCHC. Thus, combined *Amalaki Rasayana* and Capsule Max HB therapy showed clinically meaningful improvement in symptomatic and hematological parameters, supporting its potential as an adjunctive Ayurvedic intervention for sickle cell anaemia.

Keywords: Sickle cell anaemia, *sannipataja pandu*, *Amalaki Rasayana*, capsule max hb, *Amalaki Rasayana*, giloy satva, ayurveda clinical trial

Background:
The disease sickle cell anaemia is one of the most common worldwide genetic diseases. Of the two groups of sickle cell patients' Sickle cell trait (Heterozygous Hb AS) and Sickle cell disease (Homozygous HbSS) the sickle cell trait (HbAS) causes no more difficulties in daily life. However, in sickle cell disease (HbSS), patients develop many signs and symptoms such as severe body ache, chronic anaemia, generalised weakness, jaundice and hepatosplenomegaly **[1]**. These symptoms of sickle cell anaemia can be correlated with symptoms of all types of *Pandu*, *i.e., Sannipataj Pandu* **[2]**. These symptoms are very common in sickle cell disease patients in modern medicine and there is no permanent prescribed treatment. Symptomatic relief is given by treatment with analgesics, folic acids and hydroxyurea. In severe cases, on marked reduction of haemoglobin, routine blood transfusion is given. Bone marrow transplantation is another successful management strategy in some cases, but it is expensive and requires donor matching; patients must rely on folic acid and hydroxyurea throughout their life for better living **[3]**. The main aim of this research was to assess the effect of Ayurvedic herbal medicine in the management of sickle cell anaemia. The Ayurvedic approach to this disease is to provide relief both symptomatically and by increasing haemoglobin and complete blood count. Although genetic diseases cannot be cured at root level, Ayurveda management approaches relief in a short span of dosage and in a non-recurrent manner. Sickle cell anaemia is a diseased condition highly prevalent in Chhattisgarh, with 20 million of India's total population and 10% of Chhattisgarh's population suffering from the sickle cell anaemia trait **[4]**. Currently, no effective medicine has been launched for the complete treatment and management of the disease. In this clinical trial, *Amalaki Rasayana* and Capsule Max HB, which contains *Amalaki Rasayana* and *Giloy satva*, were given orally as internal administration for the treatment and management of sickle cell anaemia. An endeavour has been made to find an easy, economical and effective management for sickle cell anaemia **[5]**. Therefore, it is of interest to evaluate the therapeutic effects of *Amalaki Rasayana* and Capsule Max HB in patients with sickle cell anaemia and describe their impact on clinical symptoms and hematological parameters.

Methodology:
Study design:
This was an open label; non-comparative clinical trial (*Upashayatmaka* study) conducted at the Department of Rog Nidan evum Vikriti Vigyan, Government Ayurveda College and Hospital, Bilaspur, Chhattisgarh.

Number of patients:
Twenty-five (25) patients, irrespective of sex and religion, were selected for the clinical trial. A written consent form was taken on prescribed proforma before inclusion of each patient in the trial. A total of 30 patients were registered; 5 left the trial between assessments, so 25 patients were analysed at the end.

Ethical clearance:
The study was cleared by the Institutional Ethics Committee with Ref. No.//EC/2023/17, Bilaspur dated 1st March 2023.

Drug and posology:
The following trial drugs were administered:
[1] ***Amalaki Rasayana*:** (containing *Amalaki churna* with its *Swarasa bhavana* 3 times). Dose: 3 gm twice daily before meals in the morning and evening. *Anupana*: Cow ghee and honey in 1:2 ratios (unequal quantity).
[2] **Cap. Max HB:** (Contains: *Amalaki Rasayana* 100 mg and Giloy satva 100 mg **[4]**). Dose: 1 capsule twice daily after meals with lukewarm water.
[3] **Trial duration:** 60 days (2 months). Follow-up: Conducted on Day 15, Day 30, Day 45 and Day 60.

Inclusion criteria:

[1] Patients aged 18-50 years with a regular diet habit.
[2] Patients selected from the Pathology Laboratory of Rog Nidan evum Vikriti Vigyan and the O.P.D. and I.P.D. of the Kayachikitsa Department of the institute.
[3] Patients with haemoglobin 7-10 g/dl (moderate anaemia).
[4] Patients with a confirmed positive sickling test (Type HbAS or HbSS) presenting with signs and symptoms of sickle cell anaemia.
[5] Patients willing to participate in the clinical trial.

Exclusion criteria:
[1] Pregnant and lactating women.
[2] Patients with severe illness such as Tuberculosis, Cancer, Cirrhosis of liver or aplastic anaemia.
[3] Patients who did not come for regular follow-up.

Criteria for selection of patients:
Patients were selected on the basis of clinical features (subjective criteria) using signs and symptoms of sickle cell anaemia as per the Dutch-AIMS2-HFF Symptoms Severity Scale Method 2006: Anaemia, Pallor, Body ache (pain and crisis), Palpitation, Hand foot syndrome, Loss of appetite and Repeated respiratory infections. The following investigations (objective criteria) were also conducted before and after treatment: (1) Haematological investigations (CBC — Hb%, RBC count, MCV, MCH, MCHC); (2) Sickling test by 2% sodium metabisulphite; (3) Radiological investigations (if required).

Criteria of assessment:
For assessing the changes in clinical signs and symptoms, patients were examined at every 15-day interval over the 60-day trial. Objective and subjective signs and symptoms along with investigations were recorded. The efficacy of therapy was assessed on the basis of a suitable scoring pattern and favourable shift of grades of each symptom from 5 to 1. The grading was done using the Dutch-AIMS2-HFF Symptoms Severity Scale Method 2006. A special proforma was prepared to study the response to the given treatment and any complication. The grading proforma is shown in **Table 1.**

Statistical analysis:
The observed data were collected and collated systematically. The scoring of criteria of assessment was analysed statistically in terms of mean of BT (before treatment) and AT (after treatment), SD (Standard Deviation) and SE (Standard Error). The effect of therapy after 60 days was assessed by applying the Wilcoxon Signed Rank Test for subjective parameters and Student's paired t-test for objective parameters, comparing before- and after-treatment scores of assessment criteria. The result obtained was considered significant for $P < 0.005$.

Flow chart of clinical trial — 2 months (60 days):
Assessment for Eligibility (n=25)
↓ Enrolment
Allocation in Intervention → Receive Medication (*Amalaki Rasayana* and Cap. Max HB)
↓
Follow-up on Day 15, Day 30, Day 45 and Day 60 (2 months)
↓
Patients not meeting inclusion criteria: Excluded
Patients lost to follow-up or discontinued intervention: Excluded
↓
Analysis (n=25)

Observation:
In this clinical trial, 30 patients were registered but 5 patients left the trial during the study period; 25 patients were therefore analysed at the end. Observations based on demographic characteristics of each participant are shown in **Table 2**. The majority (64%) of patients were from the age group 18-30 years, followed by 24% from the 41-50 years group and the least (12%) from the 31-40 years group. The majority of patients (92%) were from the Hindu community and only 8% were from the Muslim community. The majority of patients were female (80%) and only 20% were male. Most patients were unmarried (56%) while 36% were married and 8% were widowed. The majority of patients (80%) were from an urban area and only 20% from a rural area. Almost all patients (96%) were literate and only 4% were illiterate. The majority (68%) belonged to the middle socio-economic class, 20% to the upper class and only 12% to the lower class. Regarding *Prakriti* (Ayurvedic constitution), two dominant *Prakriti* types were found among patients - 28% each were Vaat dominant Pitta and Vaat dominant Kapha. The second most dominant *Prakriti* was Pitta dominant Kapha with 16%. The third dominant *Prakriti* types were Pitta dominant Vaat and Kapha pradhan Vaat, each with 12%. The least dominant *Prakriti* was Kapha dominant Pitta, i.e., 4%. **Table 2** shows observation based on demographic criteria.

Results:
This was an open label non-comparative clinical trial. Twenty-five patients of *Sannipataj Pandu* (Sickle Cell Anaemia) were enrolled in the study as per inclusion and exclusion criteria. Patients were treated with *Amalaki Rasayana* and Cap. Max HB for duration of 60 days. Assessments of patients were done on the basis of subjective and objective criteria measured before and after treatment. The data collected through subjective criteria were qualitative, graded (ordinal) and paired; the Wilcoxon Signed Rank Test was therefore applied as the test of significance. The data collected through objective criteria were quantitative, continuous and paired; Student's t-test for paired data was therefore applied. In the parameters included in subjective criteria, the value of p was less than 0.05, with significant difference observed between the mean BT and AT scores in anaemia, pallor, pain crisis, palpitation, hand and foot syndrome, loss of appetite and respiratory infection. Similarly, for objective criteria, $p<0.05$ with significant differences observed between mean BT and AT scores in Hb%, RBC, MCH, MCV and MCHC. There was a marked difference of 35.71% in anaemia, 43.40% in pallor, 37.50% in bodyache, 43.86% in palpitation, 25.58% in hand-foot syndrome, 41.18% in loss of appetite and 37.78% in repeated respiratory infection, with an

overall average improvement of 37.86% across subjective criteria. Mean changes in objective parameters were 1.45 in Hb%, 0.76 in RBC, 5.16 in MCH, 6.42 in MCV and 4.62 in MCHC. This improvement is attributable to cap. Max HB, which increases *rakta dhatu* and *Amalaki Rasayana,* which acts on and clears blocked *srotas*, thereby increasing RBC count and haemoglobin. MCH, MCV and MCHC are directly proportional to RBC and haemoglobin content. **Tables 3 and 4** depict the changes in objective and subjective criteria before and after treatment respectively.

Table 1: Proforma for grading of symptoms – Dutch-AIMS2-HFF Symptoms Severity Scale Method 2006.

Sr.	Symptom	Grade	Description
	Anaemia	1	Hb is 11-16 gm.%
		2	Hb is between 8-11 gm.%
		3	Hb is between 6-8 gm.%
		4	Hb is 6-4 gm.%
1.		5	Less than 4 gm.%
	Pallor	1	No pallor
		2	Pallor with shallow pink
		3	Pallor with slight yellowish tint
		4	Pallor with ash yellowish tint
2.		5	Deep pallor (Rainy season frog-like)
	Body ache pain & crisis	1	No joint pain
		2	Pain involving only one extremity
		3	Pain involving both extremities
		4	Involvement of almost all joints of body
3.		5	Severe pain all over joints of the body
	Palpitation	1	No palpitation
		2	Slow heart beat
		3	Erratic palpitation
		4	Palpitation with chest pain
4.		5	Breathlessness
	Hand foot syndrome	1	No swelling
		2	Mild swelling on one hand or foot
		3	Swelling on upper or lower extremities only
		4	Swelling on both extremities
5.		5	Severe swelling on both extremities
	Loss of appetite	1	Appetite good
		2	Taking normal diet without any interest
		3	Taking food without interest and unable to complete it
		4	Not interested in taking food, resisting or crying
6.		5	Resisting or crying
	Repeated infection	1	No respiratory infection
		2	At interval >45 days
		3	At interval between 15 to 45 days
		4	At interval between 7 to 15 days
7.		5	At interval one week or below

Table 2: Observation of demographic criteria of study population

Demographic Criteria	Category 1	Category 2	Category 3	Category 4
Age (years)	18-30 yrs	31-40 yrs	41-50 yrs	
	16	03	06	
	64%	12%	24%	
Gender	Male	Female		
	05 (20%)	20 (80%)		
Religion	Hindu	Muslim		
	23 (92%)	02 (8%)		
Marital status	Married	Unmarried	Widowed	
	09 (36%)	14 (56%)	02 (8%)	
Habitat	Urban	Rural		
	20 (80%)	05 (20%)		
Education	Literate	Illiterate		
	24 (96%)	01 (4%)		
Occupation	Working	Non-working		
	09 (36%)	16 (64%)		
Socioeconomic status	Upper	Middle	Lower	
	05 (20%)	17 (68%)	03 (12%)	

Table 3: Before- and after-treatment observation on objective criteria using Student's paired t-test

Objective Criteria (Student's t test)	BT/AT	N	Mean	SD	SE	t	P
Hb%	BT	25	9.224	1.558	0.311	7.419	<0.0001
	AT		10.670	1.505	0.301		
RBC	BT	25	3.513	0.651	0.130	8.546	<0.0001

	AT		4.277	0.758	0.151		
MCH	BT	25	26.54	15.09	3.019	7.664	<0.0001
	AT		31.69	15.31	3.062		
MCV	BT	25	76.69	14.77	2.955	5.756	<0.0001
	AT		83.10	13.55	2.712		
MCHC	BT	25	29.48	1.590	0.318	8.396	<0.0001
	AT		34.16	2.269	0.453		

BT = before treatment; AT = after treatment; SD = Standard deviation; SE = Standard error; t = Student's t-test value.

Table 4: Before- and after-treatment observation on subjective criteria using Wilcoxon signed rank test

Subjective Criteria (Wilcoxon signed rank test)	BT/AT	N	Mean	Median	SD	W	P
Anaemia	BT	25	2.240	2	0.522	190	<0.0001
	AT		1.440	1	0.583		
Pallor	BT	25	2.120	2	0.600	210	<0.0001
	AT		1.200	1	0.408		
Bodyache	BT	25	2.880	3	0.971	171	<0.0001
	AT		1.800	2	0.408		
Palpitation	BT	25	2.280	2	0.979	171	<0.0001
	AT		1.280	1	0.408		
Hand foot syndrome	BT	25	1.720	1	0.890	55	0.0020
	AT		1.280	1	0.541		
Loss of appetite	BT	25	2.040	2	1.098	91	0.0002
	AT		1.200	1	0.408		
Repeated respiratory infection	BT	25	1.800	1	0.912	78	0.0005
	AT		1.120	1	0.331		

Discussion:

Panduroga refers to paleness or whitish-yellow appearance of the skin. *Pandu* is a *Pitta* dominant disease, specifically involving *Sadhak Pitta* and *Bhrajak Pitta*. *Pandu* is essentially a nutrition-deficient disease in which all the *nidan* vitiates the *Pitta*, blocks the minute channels (*srotas*) and along with *rasa* and *rakta dhatu* is taken between the skin and *mamsa dhatu*, leading to *pandu* (paleness of skin) **[6]**. When all *dosha* along with *Pitta dosha* are vitiated equally, this leads to *Sannipataj Pandu* or *Tridoshaj Pandu*. One suffers palpitation, lack of perspiration and roughness and dryness of skin as prodromal symptoms of *Pandu*. Although the root cause differs, the symptoms of *Sannipataj Pandu* are analogous with the symptoms of sickle cell anaemia **[7]**. Sickle cell anaemia is a type of anaemia transmitted due to hereditary causes, passed from one generation to another through genes. In this disease, RBCs have their shape deformed into a sickle shape, which carries less oxygen and restricts free flow, leading to symptoms of anaemia. The sickle-shaped cell gets attached to the vessel wall, causing vaso-occlusion and thus improper blood supply to various organs, resulting in pain in extremities, necrosis of bone and the various symptoms described above. The drugs used for treating *Sannipataj Pandu* must address both the preliminary cause and the clinical features. The main cause of *Sannipataj Pandu* is vitiated *Pitta*, which aggravates other *dosha* and hence causes *srotorodh*, which further causes obstruction and the prevalent symptoms **[8].** *Amalaki Rasayana* is an immunomodulation containing *Amalaki* (*Emblica officinalis*), which is *dhatusthapana* and a *madhur* drug; it is also *tridosha shamaka*, which clears the *srotas* by pacifying *Pitta* and thereby ultimately clears the blocked channels **[9]**. Cap. Max HB contains *Amalaki Rasayana* and *Giloy satva*. These drugs get enhanced through the processes they undergo to yield *bhasma* and *satva* respectively. They are *rasayan*, *tridosh shamaka* and *snigdha* drugs; they increase the quality of *anaras* so formed and enhance its utility in all the *dhatus* of the body. *Abhrak* additionally has *deepan* property, which increases *kayagni* and *dhatavagni* and so reduces vaso-occlusion and thus all the symptoms of sickle cell anaemia **[10]**.

Conclusion:

Amalaki Rasayana and cap. Max HB improved subjective symptoms and selected haematological parameters in patients with sickle cell anaemia, without reported adverse effects. Cap. Max HB, combined with *Amalaki Rasayana*, increased Hb%, RBC count, MCH, MCV and MCHC, but did not alter the morphology of sickled erythrocytes. The findings suggest potential therapeutic benefits; however, further controlled studies are required to establish efficacy and safety.

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Conflict of interest: There is no conflict of interest in this research work.

Ethical approval:
The study was cleared by the Institutional Ethics Committee with Ref. No.//EC/2023/17, Bilaspur, dated 1st March 2023.

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