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Original Article

Clinical Evaluation of T-AYU-HM Premium in Sickle Cell Disease (HbSS) Patients: A Retrospective Study

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ABSTRACT

Background: Sickle cell disease (HbSS) is one of the main hemoglobinopathies that affect the indigenous tribes and is a significant cause of morbidity and mortality. The effectiveness and safety of alternative medicines for sickle cell disease patients require further scientific study. The proposed study was conducted to clinically evaluate the safety and effectiveness of T-AYU-HM Premium Tablet (300 mg). **Materials and Methods:** This is a single-arm observational retrospective cohort study of 100 sickle cell disease subjects. Based on inclusion and exclusion criteria, the clinical and vital information of the patients was acquired, assessed, and reported. A follow-up period of 120±10 days was deemed sufficient. Data were analysed using a statistical package for the social sciences (SPSS). **Results:** The levels of haemoglobin (g/dL) (9.43±1.83 to 10.11±1.37) and red blood cells (/mm^3) (3.89±0.81 to 4.18±0.64) were significantly improved (p<0.05). Reticulocyte count (%) changed significantly from 4.51±3.20 to 2.84±2.34. The number of blood transfusions (7.12±26.80 to 00) and the percentage of hospitalisations (76% to 00) that occurred more than six times prior to presentation were significantly reduced. **Conclusion:** In this retrospective analysis, there were no reported adverse consequences. Patient's responses and all the clinical parameters like haematology, liver function parameters, clinical, and pain-associated symptoms with the disorder showed T-AYU-HM Premium to be an effective and safer therapy in the treatment of sickle cell anemia. Further well-planned interventional studies may become useful to justify the same.

Keywords: Sickle cell disease (HbSS), Haemoglobin, Reticulocytes.

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INTRODUCTION

Sickle cell anemia (HbSS) is an inherited autosomal disorder that causes hemolysis and chronic organ damage. HbSS is a multisystem disorder that requires no further introduction.[1] It is one of the major hemoglobinopathies causing morbidity and mortality amongst the tribal population.[2] According to the World health organization, about 5% of the world's population carries trait genes for hemoglobin disorders, like HbSS.[3] It is highly prevalent in many nations, and several observational studies have already been done on the clinical traits and show their complicated clinical features. It predominantly affects people of African, Indiana, and Arab ancestry.[4] The pathogenesis of HbSS is complicated and results in several complications like diminished immune function, delayed growth and development, infertility, and, eye and bone disorder. It also affects the cardiovascular, pulmonary, and renal systems.[5] Over the past ten years, a lot of researchers have turned their attention to the creation of medications due to sickle cell disease's orphan status. Numerous clinical trials involving sickle cell disease were either ongoing or in the planning phases. Sickle cell characteristics are frequently regarded as asymptomatic, and the silent disease is linked to several problems. Recent advances in the field, more so within the last three decades, have alleviated symptoms for countless patients, especially in high-income countries.[1] However, despite advancements in technology, treatment or research work carried out every year, severe complications of sickle cell disease claim many patients' lives.[6,7] Presently the curative options are limited and available latest options are either expensive for low-income countries or possess several side effects that a patient can't tolerate throughout their life.[8]

An alternative system of medicine approach in the management of sickle cell disease may become critical, especially in developing and low-income nations. In the present era, complementary and alternative medicine has got great limelight in the management of several chronic diseases. T-AYU-HM Premium is the traditional ayurvedic herbo-mineral formulations that help in the management of sickle cell anemia as it has an anti-sickling effect that may be able to stop the deregulation of Gardos

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channels. This herbal formulation has several ingredients which also act as a source of iron, and ascorbic acid and increase the likelihood of iron absorption. Ingredients like *Punica grantum* and *Tinospora cordifolia* extracts have a metal-chelating effect and function as potent antioxidants for Red Blood Cells (RBC). It also demonstrated hepatoprotective activity, prevent the cell lysis process, and also prevent sickling-induced activation of chemical mediators and coagulation cascades.[7-11]

To establish the formulation required physicochemical, preclinical, case study, case series has already been studied and published in refereed journals. Therefore, the present study is developed, which aims to evaluate the effectiveness and safety of AYUSH formulations. To date, no herbo-mineral formulations have been evaluated in an absolute scientific manner to present the safety and effectiveness of formulation on different forms of sickle cell anemia. T-AYU-HM Premium contains incorporation of herbs and minerals mentioned in Table 1.

MATERIALS AND METHODS

Study Oversight

The trial was conducted as per the following the declaration of Helsinki, standards of ICH-GCP, protocol guidelines, and local regulatory guidelines. Prior to the study, ethical approval was taken from Institutional Ethical Committee: ECR/942/Ins/GJ/2017/RR-20 and trial registered prospectively with clinical trial registry CTRI/2022/02/040601. The correctness and completeness of the data generated are verified by each author, and the trial's adherence to the protocol is confirmed by the sponsors. All the subjects were monitored, from the time of diagnosis until the day of their final appointment, between January/2018 to December/2020. Data are collected from a case report file maintained by the designated Clinic for sickle cell anaemia patients, the last scheduled visit's date was determined. The objective behind selection of this site for data collection is sickle cell sufferers have been receiving care at this clinic for more than two decades. Table 2 provides an overall description of the clinic to support the selection of participants and the availability of individual patient at the centre throughout the previous three years.

Inclusion Criteria

Participants diagnosed with sickle cell anaemia concluded by SCT/SCD specification testing**.** Participants between age group 5 to 80 years considered eligible. Both Male/Female participants detail considered eligible for inclusion in study. Participants who had received treatment with T-AYU-HM Premium, whose complete pathological examination data, who had regular OPD visits, are considered eligible.

Exclusion Criteria

Participants who had received treatment with other additional medications, or had incomplete pathological examination data, had irregular OPD visits are considered not eligible for inclusion in study. Participants like Pregnant / lactating women information are considered not eligible for inclusion of study.

Source of data

The Patient case records, medication charts and lab reports. The data collection process was divided into the following sections: 1) Basic demographic information: name, age, gender, identification number, and contact information; 2) Medical History: habit, diet, blood group, family history, vaccination history, rate of painful crisis, number of time hospitalisation and blood transfusion before presenting for treatment at a clinic, consanguinity, etc.

Statistical Analysis

Data were presented as Mean±SD for quantitative variables and proportion with percentage for qualitative variables. Data cleaning and analysis were performed using Microsoft Excel and Statistical Package for Social Science (SPSS) version 25 (IBM Corp., Armonk, NY, USA), respectively. A One-Way Repeated Measure Analysis of Variance was used to compare continuous variables having a normal distribution. Statistical significance was determined at a 5% level of significance.

RESULTS

A total of 100 patients with sickle cell anemia were identified and enrolled in the study. The participant's mean age was 22.17±12.08 years, with most being male patients (55%). Out of 100, 77 and 23 reported having moderate and severe pain before the visit. Of these 100, 35 showed consanguinity. Concerning the blood group, A Positive (37%) was followed by O positive (32%) and B Negative (22%) (Table 3).

Effect of Treatment on weight and vital signs

Over time (day 120), there was a significant increase in weight (40.83±13.89) compared to the baseline (39.66±14.03). The pulse rate also significantly decreased from baseline (93.76±20.47) to visit 3 (day 120) (86.77±15.57). Concerning SpO_2, no significant change was observed on day 120 (99.63±10.14) compared to baseline (98.14±1.21).

Effect of treatment on haematological parameters and liver function test

White Blood Cells (WBC) and reticulocytes were found to be significantly lower on day 120 compared to baseline. Additionally, a significant rise in Haemoglobin (Hb), Red Blood Cells (RBC), and Packed Cell Volume (PCV) were observed. Comparing the results to the baseline, a non-significant decrease in monocyte and eosinophil count was observed. Concerning liver function

test, significant reductions in serum, direct, and indirect bilirubin were observed on day 120 when compared to baseline (Table 4).

The effects of treatment on pain-associated clinical parameters

The impact of treatment on the clinical parameters related to the pain was evaluated using the Wong-Baker pain scale. Wong-Baker Pain Scale was applied to headache, AVN, abdominal colic, backache, body ache, and fatigue. The rest of the parameters including, Jaundice, Pallor, splenomegaly, general weakness, palpitation, loss of appetite, and puffiness of face was assessed by the physician on routine objectives for sickle cell patients. At day 120 (visit 3) compared to day 0 (baseline), a substantial decrease in the clinical parameters including panduta (pallor), splenomegaly, giddiness, backache, headache, general weakness, palpitation, abdominal colic, puffiness of the face, fever, chest syndrome, and AVN was observed mentioned in Tables 5 and 6.

DISCUSSION

On the basis of the current understanding of the molecular pathogenesis of Sickle Cell Disease (SCD), a number of independent approaches to treatment have been proposed and developed.[12] However, the most recent treatments are either pricey or have side effects that patients can't live with for the rest of their lives. Unfortunately, bone marrow transplantation and blood transfusion are the only treatment choices available for sickle cell disease, although they are not appropriate for everyone. A total of 100 patients with sickle cell anemia were identified and enrolled in the study. Many of these patients lack a relative who is a close enough genetic match to act as a donor. This reduces their optimum chance of having a successful transplant. This is the motive to conduct a scientific evaluation of the alternative medicine system's efficacy and safety in the treatment of sickle cell anemia.[13]

In the present study, the majority of patients were male, with a mean age of 22.17±12.08 years. With a consanguinity of 35% a study by khoreity *et al.* showed that Newborns with abnormal Hb, both heterozygotes or homozygotes, had significantly higher rates of consanguinity (28.1%).[14] Another study by Kamble *et al.* in rural India found that 7 percent of the 99 people with sickle cell anemia had a history of consanguinity.[15]

Concerning the disease prognosis after treatment, after 120 days, there was a significant increase in weight compared to the baseline

Table 1: Composition of T-AYU-HM Premium tablets.

Ingredient Name	Botanical Name	Part Used	Quantity
Abraka Bhasma	Calyx of Mica	-	25 mg
Loha Bhasma	Calyx of iron	-	12.5 mg
Haritaki	*Terminalia chebula*	Fruit	25 mg
Sunthi	*Zingiber officinale*	Rhizome	25 mg
Shatavari	*Asparagus racemosus*	Root	25 mg
Dadima	*Punica granatum*	Fruit	12.5 mg
Jaiphal	*Myristica fragrans*	Seed	25 mg
Pippali	*Piper longum*	Fruit	37.5 mg
Guduchi	*Tinospora cordifolia*	Stem	37.5 mg
Jivanti	*Leptadenia reticulata*	Root	37.5 mg
Storage condition: Store in dry and cool place. Keep away from direct sunlight. Do not refrigerate.			

Table 2: Designated clinic patient enrolment detail for 2018 to 2020.

Year	2018	2019	2020	Total
Follow-up visit of old enrolled patients	3219	3192	2650	9061
New patients enrolled	199	185	130	514
Sickle cell trait (HbAS) patients	99	94	69	172
Sickle cell disease (HbSS) patients	99	90	57	246
Beta Thalassemia patient	1	1	4	6
Sex				
Male	78	86	47	211
Female	121	99	83	303

Table 3: Demographics and Baseline Characteristics (*n*=100).

Age (years)		22.17±12.08	
Number of family members		04.92±01.55	
Gender, n (%)		Consanguinity, n(%)	
Male	55 (55.00)	Yes	35 (35.00)
Female	45 (45.00)	No	65 (65.00)
Habit, n (%)		Diet, n(%)	
Yes	4 (4.00)	B	60 (60.00)
No	96 (96.00)	V	40 (40.00)
Blood group, n(%)		Immunization, n(%)	
O positive	32 (32.00)	Continue	1 (1.00)
A positive	37 (37.00)	Done	99 (99.00)
AB positive	8 (8.00)		
A negative	1 (1.00)		
B positive	22 (22.00)		
Blood transfusion prior visit		7.12±26.80	
Rate of painful crisis before visit		Number of Hospitalization before visit	
Moderate	77 (77.00)	0	24 (24.00)
Severe	23 (23.00)	more than 6 time	76 (76.00)
Mild	00(0)		
Data are expressed in n(%) and analysed using mean±SD			

Table 4: Effect of Treatment on Laboratory and Vital Parameters.

Variables	Baseline	Visit 1 (30 days)	Visit 2 (60 days)	Visit 3 (120 days)	*p*-value
Weight (kg)	39.66±14.03	40.08±13.79	40.54±13.96	40.83±13.89	<0.001
Pulse (per minute)	93.76±20.47	91.22±13.94	92.21±16.78	86.77±15.57	0.0038
SpO_2 (%)	98.14±1.21	98.57±1.10	97.52±9.93	99.63±1.14	0.200
CBC					
Hb(gm%)	9.43±1.83	9.60±1.73	9.87± 1.53	10.11± 1.37	<0.001
RBC (per cmm)	3.89±0.81	3.96±0.80	4.00± 0.75	4.18± 0.64	0.005
WBC(per cmm)	9951.2±4223.7	9151.7±3166.9	8954.7± 3378.9	8513.9± 2877.4	0.002
Platelet (per cmm)	375460±375141.7	32500±132061.5	323155.0±122259	326100.0±106793.6	0.167
MCHC (g/dl)	32.49±3.61	33.04±1.56	32.94± 1.56	32.91± 1.54	0.254
MCH(pg)	24.43±4.92	24.61±4.60	24.95± 3.43	24.65± 3.82	0.769
MCV (fl)	74.74±12.03	75.34±11.52	75.41± 9.61	74.35± 10.70	0.809
PCV (%)	28.42±6.37	28.98± 5.39	29.86± 5.04	30.72± 4.22	<0.001
Neu (%)	60.18±12.7	60.22± 9.94	60.96± 9.59	62.36± 9.98	0.334
Eos (%)	4.06±2.68	4.36± 2.32	4.33± 2.17	3.94± 2.11	0.449
Lym(%)	34.61±12.39	34.61± 9.65	34.14± 8.49	33.20± 9.33	0.670
Mon (%)	0.85±1.87	0.87± 1.89	0.64± 1.47	0.39± 0.92	0.075
Ret (%)	4.51±3.20	2.26±5.37	2.65± 4.15	2.842.34	<0.001
LFT					

Variables	Baseline	Visit 1 (30 days)	Visit 2 (60 days)	Visit 3 (120 days)	*p*-value
S. Bil (mg/dL)	1.69±1.33	0.66±1.38	0.79±1.27	1.35±1.02	<0.001
D. Bil (mg/dL)	0.92±0.78	0.34±0.70	0.34±0.52	0.66±0.52	<0.001
I. Bil (mg/dL)	0.86±1.03	0.32±0.73	0.40±0.72	0.69±0.60	<0.001

Values are presented in Mean±SD and P-values are estimated by using one-way repeated measure analysis of variance test. Where, CBC:Complete blood counts, LFT: Liver function test, MCHC: Mean corpuscles haemoglobin concentration, MCH: Mean Haemoglobin Concentration, PCV: Packed cell volume, S.Bil: Serum Bilirubin, Mon: Monocytes Ret: reticulocytes, Lym: Lymphocytes, Eos: Eosinophils

Table 5: Effect of Treatment on Pain-Associated Clinical Parameters.

Parameters	Clinical Symptoms	Baseline	Visit 1	Visit 2	Visit 3
Body ache	No Symptoms	8 (8.00)	77 (77.00)	85 (85.00)	86 (86.00)
	Mild	24 (24.00)	16 (16.00)	10 (10.00)	7 (7.00)
	Medium	60 (60.00)	7 (7.00)	4 (4.00)	6 (6.00)
	Moderate	8 (8.00)	0 (0.00)	1 (1.00)	1 (1.00)
Giddiness	No Symptoms	98 (98.00)	99 (99.00)	100 (100.0)	100 (100.0)
	Mild	1 (1.00)	1 (1.00)	0 (0.00)	0 (0.00)
	Medium	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Moderate	1 (1.00)	0 (0.00)	0 (0.00)	0 (0.00)
Backache	No Symptoms	54 (54.00)	97 (97.00)	96 (96.00)	97 (97.00)
	Mild	19 (19.00)	2 (2.00)	3 (3.00)	1 (1.00)
	Medium	26 (26.00)	1 (1.00)	1 (1.00)	2 (2.00)
	Moderate	1 (1.00)	0 (0.00)	0 (0.00)	0 (0.00)
Abdominal Colic	No Symptoms	56 (56.00)	94 (94.00)	98 (98.00)	95 (95.00)
	Mild	40 (40.00)	6 (6.00)	2 (2.00)	4 (4.00)
	Medium	3 (3.00)	0 (0.00)	0 (0.00)	1 (1.00)
	Moderate	1 (1.00)	0 (0.00)	0 (0.00)	0 (0.00)
Headache	No Symptoms	85 (85.00)	99 (99.00)	99 (99.00)	99 (99.00)
	Mild	13 (13.00)	1 (1.00)	1 (1.00)	0 (0.00)
	Medium	2 (2.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Moderate	0 (0.00)	0 (0.00)	0 (0.00)	1 (1.00)
Chest Syndrome	No Symptoms	73 (73.00)	96 (96.00)	95 (95.00)	96 (96.00)
	Mild	12 (12.00)	3 (3.00)	4 (4.00)	4 (4.00)
	Medium	10 (10.00)	1 (1.00)	0 (0.00)	0 (0.00)
	Moderate	4 (4.00)	0 (0.00)	0 (0.00)	0 (0.00)
	Severe	0 (0.00)	0 (0.00)	1 (1.00)	0 (0.00)
AVNF	No Symptoms	76 (76.00)	82 (82.00)	87 (87.00)	90 (90.00)
	Mild	2 (2.00)	10 (10.00)	6 (6.00)	6 (6.00)
	Medium	5 (5.00)	4 (4.00)	5 (5.00)	3 (3.00)
	Moderate	11 (11.00)	2 (2.00)	1 (1.00)	1 (1.00)
	Severe	6 (6.00)	2 (2.00)	1 (1.00)	0 (0.00)

Categorical variables were summarised by frequency distribution for each categorical component (relative frequency (n) and percentage (%).

Table 6: Clinical evaluation of common clinical parameters of sickle cell anemia patients.

Parameters	Clinical Symptoms	Baseline	Visit 1	Visit 2	Visit 3
Splenomegaly	No Symptoms	53 (53.00)	74 (74.00)	88 (88.00)	93 (93.00)
	Mild	28 (28.00)	24 (24.00)	10 (10.00)	6 (6.00)
	Medium	19 (19.00)	2 (2.00)	2 (2.00)	1 (1.00)
Jaundice	No Symptoms	57 (57.00)	77 (77.00)	91 (91.00)	94 (94.00)
	Mild	26 (26.00)	18 (18.00)	9 (9.00)	5 (5.00)
	Medium	16 (16.00)	4 (4.00)	0 (0.00)	1 (1.00)
	Moderate	1 (1.00)	1 (1.00)	0 (0.00)	0 (0.00)
Pallor	No Symptoms	35 (35.00)	79 (79.00)	92 (92.00)	93 (93.00)
	Mild	50 (50.00)	18 (18.00)	7 (7.00)	6 (6.00)
	Medium	15 (15.00)	3 (3.00)	1 (1.00)	1 (1.00)
General Weakness	No Symptoms	21 (21.00)	86 (86.00)	85 (85.00)	86 (86.00)
	Mild	52 (52.00)	10 (10.00)	12 (12.00)	11 (11.00)
	Medium	27 (27.00)	4 (4.00)	2 (2.00)	3 (3.00)
	Moderate	0 (0.00)	0 (0.00)	1 (1.00)	0 (0.00)
Palpitation	No Symptoms	73 (73.00)	97 (97.00)	95 (95.00)	98 (98.00)
	Mild	24 (24.00)	3 (3.00)	4 (4.00)	2 (2.00)
	Medium	2 (2.00)	0 (0.00)	1 (1.00)	0 (0.00)
	Very Severe	1 (1.00)	0 (0.00)	0 (0.00)	0 (0.00)
Fatigue	No Symptoms	21 (21.00)	90 (90.00)	88 (88.00)	92 (92.00)
	Mild	48 (48.00)	5 (5.00)	9 (9.00)	5 (5.00)
	Medium	30 (30.00)	5 (5.00)	3 (3.00)	3 (3.00)
	Moderate	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Puffiness on Face	No Symptoms	95 (96.00)	100 (100.00)	100 (100.00)	98 (98.00)
	Mild	4 (4.00)	0 (0.00)	0 (0.00)	2 (2.00)
	Medium	1 (1.00)	0 (0.00)	0 (0.00)	0 (0.00)
Loss of appetite	No Symptoms	74 (74.00)	100 (100.00)	96 (96.00)	98 (98.00)
	Mild	26 (26.00)	0 (0.00)	3 (3.00)	2 (2.00)
	Medium	0 (0.00)	0 (0.00)	1 (1.00)	0 (0.00)
Fever	No Symptoms	84 (84.00)	98 (98.00)	96 (96.00)	94 (94.00)
	Mild	15 (15.00)	1 (1.00)	3 (3.00)	4 (4.00)
	Medium	1 (1.00)	1 (1.00)	1 (1.00)	1 (1.00)
	Moderate	0 (0.00)	0 (0.00)	0 (0.00)	1 (1.00)

Categorical variables were summarised by frequency distribution for each categorical component (relative frequency (n) and percentage (%).

with significant decrease in pulse rate from baseline (93.76±20.47) to visit 3 (day 120) (86.77±15.57). However, no significant change in SpO_2 was observed on day 120 (99.63±10.14) compared to baseline (98.14±1.21).

A high reticulocyte count in someone with sickle cell disease suggests increased hemolysis[1]. Reticulocyte counts are used as a vital marker to predict sickling-induced complications. Our results on various clinical parameters show that WBC and reticulocytes were found to be significantly lower on day 120 compared to baseline. Similar results were observed in the study conducted by Desai *et al.*[7] which suggests that after treatment with herbal medication there is no acute RBC destruction.

In our study there was a significant rise in Hb, RBC, and PCV was also observed. The degree of hemolysis is inversely related to Hb concentration and packed cell volume in sickle cell anemia patients.[16] The study by Akinbami *et al.*, suggests that Homozygous SCD patients have lower values of Hb concentration, PCV, and red cell indices, but higher values of white cell count

and platelets compared to hemoglobin phenotype AA controls.[17] This shows the positive effect of the treatment on the blood parameters.

Sickle cell hepatopathy is an umbrella term defined as liver dysfunction and hyperbilirubinemia due to the intrahepatic sickling process during SCD.[18] In our study, concerning the liver function test, there were significant reductions in serum, direct, and indirect bilirubin after treatment compared to baseline, which indicates that highly perfuse organs like the liver didn't encounter any adverse effects from the treatment.

The impact of treatment on the clinical parameters related to the pain was evaluated using the Wong-Baker pain scale. Sickle cell anemia patients frequently experience Panduta (Pallor) and Durbalaya (general weakness), Kamala (jaundice), discomfort (from vascular blockage), and Plihodar (splenomegaly). Current medications (analgesics) that are used to relieve pain and to help restore RBCs don't reduce the disease complications.[9] In contrast, the present treatment showed a positive effect, at day 120 (visit 3), along with substantial decrease in all the pain-associated clinical parameters.

The present study shows the necessity of educating the Indian population (tribal and nontribal groups) on consanguinity and its influences on the progression and prognosis of several genetic disorders, including sickle cell disease. In the current period, there are only a few registered and completed clinical trials or successful studies on herbal medication. The present study recommends a strong body of scientific research to support using herbs-mineral formulations for sickle cell anemia.

CONCLUSION

The T-AYU-HM Premium treatment remarkably affected sickle cell disease patients, demonstrating both its effectiveness and safety. In the retrospective analysis, there were no adverse consequences and the subjects' vital signs remained stable throughout the course of treatment. There was a significant clinical improvement since none of the subjects developed any new complications or required hospitalization. Further well-planned interventional studies may become useful to justify the same.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

HbSS: Sickle cell anemia; **SCT:** Sickle cell trait; **SCD:** Sickle cell disease**; OPD:** Outpatient Department; **Hb:** Hemoglobin; **RBC:** Red blood corpuscles; **PCV:** Packed cell volume; **AVN:** Avascular necrosis.

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