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Original Research Article

Impact of hydroxyurea use on severity and hematologic profile in children with sickle cell disease at University of Benin Teaching Hospital, Benin city, Nigeria

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ABSTRACT

Background: Sickle cell disease (SCD) is a major cause of morbidity and mortality among children in sub-Saharan African. Hydroxyurea (HU) remains the cornerstone of disease- modifying therapy, but its utilization, hematologic impact and relationship with disease severity among Nigerian children are not fully characterized. This study assessed the impact of hydroxyurea use on disease severity and haematologic profile in children with SCD attending the University of Benin of teaching Hospital, Benin city.
Methods: This cross- sectional study included 225 children with SCA aged 1-18 years in steady state. Data were obtained on socio- demographic characteristics, HU use and disease severity were using structured proforma and medical records. Disease severity was assessed using Adegoke's scoring system while haematologic parameters including Packed cell volume and White blood cell counts were documented. Statistical associations between HU, hematologic indices and disease severity were analysed using Chi-square tests, with significance set at $p<0.05$.
Results: The mean age was 9.5±4.5 years: 57.8% were male and 57.3% belonged to the middle socioeconomic class. Most patients had mild (51.1%) or moderate (47.6%) disease with severe disease in only 1.3%. disease severity was significantly associated with gender (p=0.029). Hydroxyurea use was high (61.3%), more frequent in females (p=0.032). HU use was significantly associated with disease severity (χ^2=9.422; p=0.009). Higher PCV was linked with milder disease (p= 0.004) whereas elevated WBC counts were associated with more severe disease (p<0.001).
Conclusions: HU therapy, higher PCV and lower WBC counts are associated with milder disease among children with SCD. These findings reinforce Hydroxyurea clinical benefits and highlight the value of simple haematologic indices for disease monitoring in resource poor settings.

Keywords: Disease severity, Hydroxyurea, Sickle cell anaemia, Packed cell volume, White blood cell count

INTRODUCTION

Sickle cell disease (SCD) is one of the commonest inherited disorders in the world. It is estimated that more than 305,000 children are born with this each year. With about 75% of these living in Sub-Saharan Africa.[1] SCD is caused by mutation in the beta globin gene, where hydrophilic glutamic acid is replaced by hydrophobic valine. HbS has the unique property of forming long branching polymers in the deoxygenated state.[2] These damage the red cell causing it to dehydrate and become rigid, fragile and obstructive. This leads to vaso-occlusion, an increased rate of intravascular chronic haemolysis, resulting in complex inter- related pathologic events including inflammation, coagulopathy, vascular-endothelial dysfunction, platelet activation, oxidative damage recurrent pain episodes, irreversible multi-organ damage and early death.[3]

The clinical course of the disease varies greatly from patient to patient depending on the sickle cell haplotypes, haemoglobin F levels and geographic location all of which impacts the development of sickle cell complications eventually culminating in multiple end organ damages and early death.

Established treatment options have improved outcomes but the availability of these options is not uniformly present in most locale. The use of hydroxyurea is routine for sickle cell children in most developed countries but in our locales, it is not routine. Other treatment measures and the use of recently discovered medications are beyond the reach of most African children living with sickle cell disease.

Hydroxyurea (HU) is a chemotherapeutic agent that, among its various effects stimulate the synthesis of foetal haemoglobin. This increase in foetal Hb levels mitigates sickling of red blood cells, consequently lowering the occurrence of complications associated with SCD in children. Studies have documented that the benefits of HU to patients with SCD outweighs the risks. Amongst the observed benefit of HU to patients with SCA are decreased incidence of pain crisis, acute chest syndrome, reduced need for blood transfusions, decreased hospital stays, less damage to organs, reduced costs of patients care and reduction in early mortality.[4-7] HU has been documented to cause significant improvement in different haematological parameters such as haemoglobin concentration, increase production of Haemoglobin F, and increase mean corpuscular volume.[8]

Sickle cell severity impacts on presence of severe complication and mortality in sickle cell children. Several factors contribute to the disease severity. These include the sickle cell haplotype, the co-inheritance of haemoglobin F, and alpha thalassemia, and geographic location of the sufferer vis a viz the presence of effective treatment protocols. Determination of the sickle cell haplotype requires DNA studies that are usually unavailable in our locale, while presence of alpha thalassemia also require DNA study but can be inferred by presence of low mean corpuscular volume and elevated haemoglobin A2 levels. This makes it difficult to adequately characterize patients. However, several scoring systems have been developed nationally and international, but none is universally accepted. Adegoke and Kuti in 2013 introduced a scoring system to evaluate the clinical severity of SCA in Nigerian children using simple clinico- laboratory parameters which included frequency of crisis, hospital admissions and transfusions in the preceding one year, degree of liver and splenic enlargement, life- time cumulative frequency of specific complications of SCA, Packed cell volume and white blood cell count. The total scores ranged from 0-24 with less than 8 graded as mild, 8-17 moderate and more than 17 severe disease.[9] This scoring system was adopted for this study.

Given that differing degrees of severity is found among children living with SCA and the disparity in the frequency of use of HU among health facilities in Nigeria, this study therefore aims to: 1) determine the proportion of children taking HU, 2) determine if there is a relationship between HU intake and severity of disease, 3) determine if there is a relationship between packed cell volume, total white blood cell and HU intake.

METHODS

Study area

The study was conducted at the Paediatric Haemato-oncology Clinic of University of Benin Teaching Hospital (UBTH), a tertiary referral centre located in Benin City, Edo State, Nigeria. UBTH provides comprehensive care for children with sickle cell disease, including routine follow-up, laboratory monitoring, and parental education/counselling.

Study design

This study was a hospital-based descriptive cross-sectional study conducted among children with sickle cell disease who are in steady state between April to September 2025.

Study population

The study population consisted of children aged 1–18 years diagnosed with sickle cell anaemia (HbSS) who attended the Paediatric Haemato-oncology Clinic during the study period. Caregivers (parents or guardians) of eligible children were also included, as they are primarily responsible for daily caring of the children.

Inclusion criteria

Children aged 1–18 years with confirmed diagnosis of sickle cell disease. All sickle cell disease children in steady state (no crisis, infection for at least 4 weeks and no blood transfusion in the preceding 3 months). Caregivers who gave informed consent.

Sample size determination

The sample size was calculated using the single population proportion formula:

$$N = \frac{Z^2 pq}{d^2}$$

where n is the minimum sample size, Z is the standard normal deviation at 95% confidence interval (1.96), p is 0.5 (50% prevalence when prevalence is unknown)

q = 1 − p, and d is the margin of error set at 0.05.

$$n = \frac{(1.96)^2 \, x \, 0.5 \, x \, 0.5}{(0.05)^2} = 384$$

Substituting For Finite population

$$Nf = \frac{n}{1 + \frac{n}{N}} = 204$$

Adjust for non-response= 10%

N= 204+21= 225 participants

Sampling technique

The participants were recruited consecutively from the paediatric sickle cell clinic until the sample size was met.

Data collection

A structured proforma was used to obtain the socio-demographic data, relevant clinical data. The parents provided required clinical information which was corroborated with the information obtained from the case note. Major sickle cell events like severe VOC, acute chest syndrome, stroke, meningitis, osteomyelitis was documented. Each child was examined for the presence of large spleen and liver. The full blood count done on the day of presentation at the clinic was used to assess hematologic parameters. Full blood count was done using an automated blood analyser

The sickle cell severity was determined by Adegoke's Scoring system:9 the scores was interpreted as <8- mild disease; 8-17- moderately severe. disease; >17-severe disease

The sickle cell complications were those determined in Adegoke's scoring system-gall stones, osteomyelitis, priapism, leg ulcers, meningitis, acute chest syndrome (ACS), stroke (CVA)

Socio-economic status was determined by Oyedeji classification10 which assesses socioeconomic status based on parental occupation and educational attainment. Each parent was scored separately from I to V for both occupation and level of education. The four scores were summed and averaged to obtain a mean score. The approximated mean determined the socioeconomic class.

Data analysis

The data were entered into the Excel spreadsheet. IBM Statistical Package for Social Sciences (SPSS) version 26.0 was used to analyse the data. Categorical variables such as sex, socioeconomic class, disease severity categories and presence of complications were summarized using frequencies and percentages. The severity of sickle cell disease was categorized into mild, moderate and severe based on Adegoke's scoring system. Associations between categorical variables (such as disease severity, sex, presence of complications) were tested using the Chi-square test. Comparison of means between groups was performed using Student's t-test. A p value of <0.05 was considered statistically significant.

Ethical considerations

Ethical approval was sought and obtained from the Health Research Ethics Committee of University of Benin Teaching Hospital (ADM/E 22/A/VOL. VII/148312107). Informed consent was obtained from caregivers, and assent was obtained from children aged 7 years and above. We declare that the study was performed in accordance with the ethical standards outlined in accordance with the ethical standards outlined in the 1964 Declaration at Helsinki.

RESULTS

Socio-demographic characteristics of study participants

A total of 225 SCA children aged between 1 and 18 years old were studied. The mean age of the study participants was 9.5±4.5 years. Amongst the study participants, 57.8% were males, while the rest were females. Majority of the participants (57.3%) belonged to the middle socioeconomic class (Table 1).

Table 1: Socio-demographic characteristics of subjects.

Variables	Frequency, N (%)
Age group (years)	
1- 6	68 (30.2)
7-12	92 (40.9)
13-18	65 (28.9)
Gender	
Male	130 (57.8)
Female	95 (42.2)
Parent's social class	
Lower	72 (32.0)
Middle	129 (57.3)
Upper	24 (10.7)

Sickle cell disease severity

Of the study participants, 51.1% had mild disease and 1.3% had severe disease. The rest had moderately severe disease. Two (1.5%) of the males and 1 (1%) of the females had severe disease, while 40% of the males and 57.9% of the females had moderately severe disease. There was statistically significant difference between disease severity and gender, p=0.029 (Table 2).

Hydroxyurea use and its duration of use

Majority of the study participants (61.3%) use hydroxyurea and significantly more females (69.5%) than

males use hydroxyurea; p=0.032. Majority of the participants have been on hydroxyurea for >12 months. However, there is no difference in the duration of intake of hydroxyurea between males and females; (p=0.118) (Table 3).

Table 2: Sickle cell disease severity by sex.

Disease severity	Sex		χ^2	P value
	Male (%)	Female (%)		
Mild	76 (58.5)	39 (41.1)	7.0479	0.029
Moderate	52 (40.0)	55 (57.9)		
Severe	2 (1.5)	1 (1.0)		

Table 3: Hydroxyurea use and its duration of use by sex.

	Sex		χ^2	P value
	Male (%)	Female (%)		
Hydroxyurea use				
Yes	72 (55.4)	66 (69.5)	4.5943	0.032
No	58 (44.6)	29 (30.5)		
Duration of use				
Not applicable	58 (44.6)	29 (30.5)	5.865	0.118
<6 months	13 (10.0)	16 (16.8)		
6-12 months	15 (11.5)	10 (10.5)		
>12 months	44 (33.9)	40 (42.1)		

Table 4: Hydroxyurea intake and disease severity.

HU use	Disease severity			χ^2	P value
	Mild (%)	Moderate (%)	Severe (%)		
No	55 (47.8)	32 (29.9)	0 (0.0)	9.422	0.009
Yes	60 (52.2)	75 (70.1)	3 (100)		

HU-hydroxyurea

Table 5: Hydroxyurea intake and disease severity by sex.

Sex	HU use	Disease severity			$\chi2$	P value
		Mild (%)	Moderate (%)	Severe (%)		
Female	No	16 (55.2)	13 (44.8)	0(0.0)	3.698	0.157
	Yes	23 (34.9)	42 (63.6)	1 (1.5)		
Male	No	39 (67.2)	19 (32.8)	0 (0.0)	4.365	0.113
	Yes	37 (51.4)	33 (45.8)	2 (2.8)		

HU-hydroxyurea

Table 6: Haematologic profile of subjects by sex.

Hematologic parameter	Sex		$\chi2$	P value
	Males (%)	Female (%)		
PCV (%)				
<18	2 (1.5)	3 (3.2)	3.479	0.176
18-23	69 (53.1)	60 (63.2)		
>24	59 (45.4)	32 (33.7)		
Total WBC (/mm3)				
<11,000	64 (49.2)	41 (43.2)	2.435	0.296
11,000-15,000	53 (40.8)	38 (40.0)		
>15,000	13 (10.0)	16 (16.8)		

PCV-packed cell volume, WBC-white cell count

Table 7: PCV and disease severity.

PCV (%)	Disease severity			χ^2	P value
	Mild (%)	Moderate (%)	Severe (%)		
<18	3 (2.6)	2 (1.9)	0 (0.0)	15.318	0.004
18-23	52 (45.2)	74 (69.1)	3 (100)		
>24	60 (52.2)	31 (29.0)	0 (0.0)		

Table 8: White blood cell count and disease severity.

Total WBC (/mm^3)	Disease severity			χ^2	P value
	Mild (%)	Moderate (%)	Severe (%)		
<11000	67 (58.3)	38 (35.5)	0 (0.0)	35.681	0.000
11000-15000	42 (36.5)	49 (45.8)	0 (0.0)		
>15000	6 (5.2)	20 (18.7)	3 (100.0)		

Table 9: Association between hydroxyurea use and haematological parameters.

	Hydroxyurea use		χ^2	P value
	Yes (n=138) N (%)	No (n=87) N (%)		
PCV (%)			1.22	0.543
<18	2 (1.5)	3 (3.5)		
18-23	78 (56.5)	51 (58.6)		
>23	58 (42.0)	33 (37.9)		
Total WBC (/mm^3)			0.05	0.975
<11,000	65 (47.1)	40 (46.0)		
11,000-15,000	55 (39.9)	36 (41.4)		
>15,000	18 (13.0)	11 (12.6)		

Hydroxyurea intake and disease severity

52.2%, 70.1% and 100% of SCD patients with mild, moderate, and severe disease respectively were on hydroxyurea (Table 4).

The difference in the use of hydroxyurea among the various disease categories was statistically significant. In males and females there was no significant association between HU intake and disease severity (χ^2=4.365; p=0.113), (χ^2=3.698; p=0.157) respectively (Table 5).

Haematologic profile of the subjects

Majority of the study participants (57.3%) had a packed cell volume of between 18-23% and there was no significant difference between gender.

One hundred and five (46.7%) of the participants had WBC of <11,000/mm^3, 12.9% had WBC count of >15,000/mm^3 (Table 6).

Packed cell volume and disease severity

All the patients with severe disease had PCV between 18-23%. For patients with mild disease, majority (52.2%) had PCV>24%, while those with moderately severe disease, majority had PCV between 18-23%. The difference in the PCV between the disease categories was statistically significant (chi square with Yates's correction).

In males, there was no significant association between PCV and disease severity (χ^2=5.027; p=0.285). In females, there was a significant association between PCV and disease severity (χ^2=11.143; p=0.025). Patients with higher PCV tend to have milder severity. Similarly, there was a significant association between PCV and disease severity when each gender was combined (χ^2=15.318; p=0.004) (Table 7).

WBC count and severity

Majority (58.3%) of subjects with mild diseases had total WBC of <11,000/l majority of subjects with moderate disease had WBC between 11,000 and15,000/l and while all the patients with severe disease had WBC>15,000/l. The difference in the total WBC in the disease categories was statistically significant (Table 8).

Haematologic parameters and hydroxyurea use

There was not statistically significant association between hydroxyurea use and PCV category among sickle cell children (χ^2=1.22, p=0.543). Similarly, no statistically significant association was observed between hydroxyurea use and Total WBC category among sickle cell children (χ^2=0.05, p=0.975) (Table 9).

DISCUSSION

A total of 225 children with SCD with mean age of 9.5±4.5 years; 57.8% male and 57.3% middle socioeconomic class. This age distribution (school-age predominance) and paediatric male predominance are commonly reported in clinic- based paediatric SCD series and reflect who attends follow-up clinics rather than true population incidence. Clinic series frequently show school- age peaks because of severe events cluster in early childhood and older children remain under follow up. Of these, 98.7% has mild-to-moderate disease severity (51.1% mild and 47.6% moderate) which is consistent with many clinic- based paediatric SCD cohorts when using composite severity indices such as a report by Nnajekwu et al in Enugu, Adeodu et al in Ile-ife.[4,11] This could be attributed to the fact that most of the haplotypes in Nigeria are of Benin type, which has intermediate levels of foetal haemoglobin and confers moderate disease severity. In contrast, Adegoke et al at Ile-Ife documented that 33.9% of their subjects had mild disease, 55.7% had moderate disease and 10.4% severe disease.[8] A study in Yemen by Al-Saqladi et al reported that a higher proportion of participants were in severe disease category unlike the present study that had only 1.3% with severe disease.[12] This difference may be due to genetic variations of haplotypes in Yemen which is a combination of the African and Saudi-Indian haplotypes (ARAB) and confers disease severity ranging from mild to severe disease. The use of certain medications like hydroxyurea by some SCD patients in the various studies and other genetic abnormalities such as glucose-6-phosphate dehydrogenase deficiency, thalassemia and foetal haemoglobin may also modify the clinical presentation. Moreso, Ezeuko et al in Imo found 88.2% with mild disease and 11.8% with moderate disease and Olasinde et al at Ogbomoso found 80% with mild disease and 20% moderate.[13,14] This may be explained by the fact that their study design may have excluded those with severe disease like previous cerebrovascular accidents which could have moved the patient to more severe disease spectrum.

Sixty one percent of participants in this study were on hydroxyurea with no significant association between duration of HU intake and gender. This level of uptake is encouraging, as previous Nigerian studies have reported much lower utilization, largely due to high costs, limited availability and lack of liquid formulations suitable for younger children. However, the figure remains lower than that reported by Chianumba et al in a multi-centered study in Nigeria, where the authors documented 89.7% HU uptake likely reflecting differences in patient populations, including adults.[15] In high-income countries, HU is widely prescribed and forms core component of SCD management, with substantial evidence demonstrating reductions in vaso-occlusive crises, acute chest syndromes, hospitalizations and transfusion needs. The higher HU among females in the current study differs from some reports where males predominated as documented by Adewoyin et al and Adigun et al.[5,6] Gender differences in HU use may reflect health- seeking behaviours, adherence pattern or fertility concerns particularly in adolescent males.

In our cohort, the predominant steady state PCV was 18-23%, consistent with chronic moderate anaemia typical of paediatric HbSS. This distribution mirrors reports from Nigerian and other sub-Saharan cohorts where mean steady-state PCV are commonly in the low- to mid-20s, reflecting ongoing haemolysis and reduced RBCs survival in HbSS.[16,17] Chronic haemolysis is the principal biological driver of low steady state PCV but the observed values are also influenced by background nutritional status, endemic infections like malaria- all documented modifiers of PCV in African series.[11,19] Clinically, low steady state PCV identifies children at increased risk of adverse outcomes and signals the need for closer surveillance, consideration of transfusion where indicated and optimization of disease- modifying therapy such as hydroxyurea.[20,21] Leukocyte profile in our study showed that while many children had WBC in the expected steady state range, a notable subset had leucocytosis (>15,000/mm^3). Elevated WBC count is a long-recognized prognostic marker in SCA and has been associated with higher risk of VOCs, ACS, CVA and progressive organ damage in multiple cohorts and the Cooperative Study of Sickle cell Disease predictive models.[21,22] Mechanistically, leucocytosis reflects chronic inflammation, immune activation and endothelial interaction that promote vaso-occlusion and tissue ischemia; frequent or subclinical infections common in some settings further amplify WBC counts and clinical risk.[23]

Strengths of the study

The use of Adegoke's scoring system, which has been developed and standardized for Nigerian children ensured a context- appropriate and objective assessment of disease severity. Data were obtained from caregiver reports and patients case notes, improving the accuracy of clinical information and reducing reliance solely on recall. The sample size of 225 participants was sufficient to detect meaningful associations and is comparable to similar hospital-based studies in Nigeria.

Limitations of the study

Being a hospital-based study, the findings may not be fully generalizable to all children with SCD in the community, particularly those who do not access tertiary care. The cross-sectional nature of the study limits the ability to establish causal relationships between variables and disease severity. Important factors such as foetal haemoglobin, alpha thalassemia status and haplotypes were not assessed due to resource constraints which may affect interpretation of disease severity.

CONCLUSION

Majority of children with SCD in this study had mild to moderate disease severity. HU use was common and

showed a significant association with reduced disease severity. Lower packed cell volume was significantly associated with greater disease severity suggesting that anaemia severity reflects disease burden. Higher WBC counts correlated positively with disease severity, consistent with the inflammatory nature of SCD. Low PCV and high WBC counts were significantly associated with moderate- to- severe disease supporting their role as markers of disease severity.

Recommendations

Hydroxyurea therapy should be encouraged and routinely integrated into the standard management of children with SCD. PCV and WBC count should be routinely monitored during clinic visits, as these may serve as useful indicators of disease severity and treatment response. Continuous health education should be provided to caregivers on the benefits, safety and importance of adherence to HU therapy in reducing complications and improving quality of life.

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