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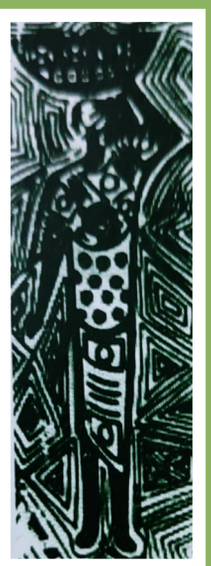

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Awareness, Acceptability and Outcome of Newborn Screening for Sickle Cell Disease in Benue State, Nigeria

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Abstract

Background: Sickle cell disease (SCD) is the most common inherited disorder in tropical Africa, and Nigeria, being the most populous African country, contributes about half of the estimated 300,000 newborns with SCD annually. Early identification of SCD through Newborn Screening (NBS) is routine in developed countries, and subsequent delivery of preventive measures and comprehensive care is highly effective in reducing morbidity and early mortality. Despite the proven efficacy of NBS, large- scale implementation in Nigeria is lacking owing to inadequate financial, laboratory, and technical resources. However, inexpensive, easy-to-use tests have been developed that can differentiate common haemoglobin genotypes in newborn babies and can be performed at remote sites.

Objective: To pilot newborn screening in Benue State, Nigeria using SickleScan (BioMedomics, Morrisville, NC, USA).

Methods: This multicenter cross-sectional study involved newborns attending immunisation clinics at three selected facilities in Benue State. Newborns aged 0-6 weeks who presented for immunisation during the study period were screened using the Sicklescan.

Results: A total of 959 newborns were screened over 9 months, with 476 males and 483 females. The distribution of haemoglobin phenotypes showed HbAA 84.4% (n = 810), HbAS 14.1% (n = 135), and HbSS 1.5% (n = 14). The acceptance of NBS was 98.6%, and post-test counselling was performed.

Conclusion: The incidence of sickle cell anaemia among neonates in Benue State, Nigeria, was 1.5%. Newborn screening was widely accepted and can be easily incorporated into immunisation programs for large-scale screening.

Keywords: Haemoglobin phenotype, Newborn screening, Sickle cell disease, SickleSCAN.

Introduction

Sickle cell disease (SCD) is a life-threatening monogenic condition that affects millions of people globally.[1] It is the commonest inherited disorder in tropical Africa, and Nigeria, being the most populous African country, contributes about half of the estimated 300,000 newborns with SCD annually, with an annual infant death of about 100,000, which represents 8% of the infant mortality in the country.[2,3] In Nigeria, about 150,000 children are born with SCD annually, with about a 25% disease carrier rate and a 2-3% sufferer rate among Nigerians.[3 – 6]

SCD occurs when an individual inherits the variant sickle haemoglobin (HbS) from one parent and another variant haemoglobin (Hb) from the other parent. The latter variant Hb may also be an HbS or a different variant, such as HbC

or Hb S-β thalassemia.[6,7] The inheritance of Hb S from both parents, ie Hb SS, is referred to as sickle cell anaemia (SCA), and it is the most typical and most severe form of SCD.[3, 8] It is a multi-systemic chronic and progressively debilitating medical condition featuring ongoing hemolytic anaemia and recurrent acute vaso-occlusive events with considerable morbidity from insidious but inexorable organ damage.[9] Children with SCD have repeated episodes of painful crisis, anaemia and increased susceptibility to infection, with an estimated 50-90% dying before the age of 5 years in Africa.[10] It is estimated that only 50% of children with SCD live past the age of 10 years in Nigeria, compared to over 96% surviving into adulthood in the UK and the USA.[11] The high morbidity and mortality are directly related to late diagnosis and the absence of a comprehensive care program, leading to recurrent crises, infections and end-organ failure.[11–13] SCD can be diagnosed using a blood sample and biochemical methods such as isoelectric focusing, capillary electrophoresis or high-performance liquid chromatography (HPLC), which are still widely used, especially in our clime for blood analysis. More recent methods include mass spectroscopy and molecular genetic analysis.[14] Newborn screening is paramount for early diagnosis and enrollment of affected children into a comprehensive care programme.[15] Standard care for sickle cell anaemia includes the use of penicillin prophylaxis, pneumococcal vaccines, malaria prophylaxis, as well as the use of disease-modifying therapies such as hydroxyurea and long-term blood transfusions.[2,7]

In high-resource countries, early identification of SCD through Newborn Screening (NBS) is routine and subsequent delivery of preventive measures and comprehensive care is highly effective in reducing morbidity and early mortality.[16] However, in Nigeria, like in other African countries, most patients do not have the benefit of an early diagnosis, and even those diagnosed do not receive chemoprophylaxis with penicillin or non-curative but disease-modifying treatments such as hydroxyurea. [17] Despite the proven efficacy of NBS, large-scale implementation remains infeasible in many sub-Saharan countries due to inadequate financial, laboratory and technical resources.[16] Though having the highest birth prevalence of SCD in the world, with an estimated 150,000 annual births of babies with sickle cell anaemia, newborn screening up till now has been significantly impaired in Nigeria because screening methods are technologically and financially intensive.[15] Even though there are six designated centers for NBS equipped with an HPLC machine (Bio-Rad, Hercules, CA, USA) located in each of the six geopolitical zones of the country, NBS is still bedeviled with many challenges such as poor awareness about NBS facilities, no specific budgetary allocation, erratic power supply, expired reagents and absence of mechanisms to collect samples from babies regularly etc. [15,18]

However, inexpensive easy-to-use tests which can differentiate common hemoglobin genotypes in newborn babies and that can be done at remote sites have been developed.[15] These point-of-care tests are based on different diagnostic principles, such as erythrocyte density, differential mobility of haemoglobin S (HbS) and haemoglobin A (HbA) through the filter paper and antibody-based immunoassay.[15] Newborn screening with a point-of-care (POC) test, performed at health facilities and providing results to caregivers during the same visit, would allow earlier detection, education, and management to prevent early mortality in infants and children with SCD more effectively.[19] POCT has been used in a few pilot studies in Nigeria, and the two evaluated (HemoTypeSC and SickleSCAN) demonstrated 100% specificity and sensitivity with HPLC.[15, 20] Despite the testing of two POCTs, awareness and uptake are generally low, and in Benue State,

there are no programs or facilities for newborn screening; hence, most children get diagnosed with sickle cell anaemia following the onset of complications or in the course of investigation for other conditions. Despite a sickle cell trait prevalence of 18.7%, a recent study involving pregnant women revealed that the majority (97.0%) of participants were unaware of their haemoglobin genotype.[21] Therefore, this study sought to determine the awareness, acceptability and outcome of newborn screening for SCD in Benue State using SickleSCAN (BioMedomics, Morrisville, NC, USA).

Methods

Study design

This was a multicentre cross-sectional study carried out in 3 health facilities purposively selected from the three major towns in Benue State from February 2024 to November 2024.

Study population

These comprised mothers and their babies aged 0-6weeks, including those delivered in the facility and those delivered outside the facility but brought to the facility for immunisation.[22]

Study setting

Benue State is located in the North Central region of Nigeria with an average population density of 99 persons per Km² and an estimated population of about 4.2 million people according to the 2006 national population census.[23] It is inhabited predominantly by the Tiv, Idoma, and Igede people, although other ethnic groups such as Hausa, Igbo, Igala, Jukun, Etulo and Abakpa are also found in the state.[24] Most of the population consists of civil servants, while others are traders and farmers. Additionally, 59.6% of the population falls into the poor wealth quintile.[24, 25] The state has a literacy level of 69.9%, a total fertility rate of 4.8%, and antenatal coverage of 67.5%, with 61.6% of deliveries being facility-based.[26]

Ethical considerations

Ethical clearance for the study was obtained from both Benue State University Teaching Hospital (BSUTH) Health Research Ethics Committee (BSUTH/MKD/HREC/2023/024) and Benue State Ministry of Health. Informed consent was also obtained from the parents after counselling.

Data collection

One selected health worker from the immunisation unit from each of the three selected facilities, namely the General Hospital Gboko, Federal University of Health Sciences Teaching Hospital Otukpo, and the Benue State University Teaching Hospital, was recruited following approval and trained before the commencement of the study on the use of SickleSCAN for newborn screening in accordance with the manufacturer's manual. The SickleSCAN is a multiplexed, qualitative, point-of-care immunoassay used in the rapid diagnosis of sickle cell disease.[27] The test is made of three indicators which detect the presence of haemoglobin A, S, and C.[27] The test can be completed in under 5 minutes, giving real-time results, and it uses a small amount of whole blood from a fingerstick, heelstick, or venipuncture.[27] The BioMedomics Sickle SCAN test kit contains: Sickle SCAN cartridge, Capillary Sampler, Pre-treatment Module (containing buffer solution), and Package Insert. [27] Following the commencement of the study, newborn babies delivered in the selected facilities and those brought in for immunisation were screened regularly using the SickleSCAN tool. Parental consent was obtained, and data were collected using a structured interviewer-administered questionnaire. Test results were documented and given within five minutes.[27] Mothers whose babies were found to have sickle cell anaemia were counselled to enrol the babies into care at the SCD clinic.

Statistical analysis

The study used the IBM SPSS Statistics version 23 software (Armonk, NY: IBM Corp) to analyse the data. Fisher's exact test was used to test for associations where appropriate, and the level of significance was set at $p<0.05$.

Results

Nine hundred and fifty-nine newborns were screened, with 49.6% (n = 476) males and 50.4% (n = 483) females. Most of the newborns belonged to Tiv ethnic group (598, 62.4%), followed by Idoma (278, 29.0%) and Igbo (36, 3.8%). Most of the mothers did not know their haemoglobin genotype (735, 76.6%), and most fathers' haemoglobin genotype was also unknown (785, 81.9%), as shown in Table I.

Table Ia: Socio-demographic characteristics of newborns and parents

Variables	Frequency	Percentage
Age (days)		
1-7	369	38.5
8-14	129	13.5
15-21	62	6.5
22-28	30	3.1
29-36	41	4.3
37-42	328	34.2
Sex		
Male	476	49.6
Female	483	50.4
Ethnicity		
Tiv	598	62.4
Idoma	278	29.0
Igede	19	2.0
Yoruba	5	0.5
Igbo	36	3.8
Hausa	3	0.3
Others	20	2.1

Table Ib: Socio-demographic characteristics of newborns and parents

Variables	Frequency	Percentage
Mother's genotype status		
Unknown	735	76.6
Known	224	23.4
Mother's genotype (n = 224)		
AA	165	73.7
AS	56	25.0
SS	3	1.3
Father's genotype status		
Unknown	785	81.9
Known	174	18.1
Father's genotype (n = 174)		
AA	147	84.5
AS	25	14.4
SS	2	1.1
Mothers' parity		
1	346	36.1
2	219	22.8
3	153	16.0
4	129	13.5
≥5	112	11.7

Awareness about sickle cell disease was high (718, 74.9%), but awareness about newborn screening was poor (317, 33.1%), as shown in Figure 1. The outcomes of screening showed the majority of the newborns had haemoglobin genotype AA (810, 84.4%), while the prevalence of sickle cell anaemia among the newborn population was 1.5% (14/959), as shown in Figure 2.

There were more male newborns with sickle cell anaemia (n = 8) compared to females (n = 6), but the association with sex was not statistically significant. There was a significant association (p = 0.049) between sickle cell anaemia and ethnicity. Most of the newborns who had sickle cell anaemia belonged to parents with unknown genotypes, but this relationship was not statistically significant, as shown in Table II.

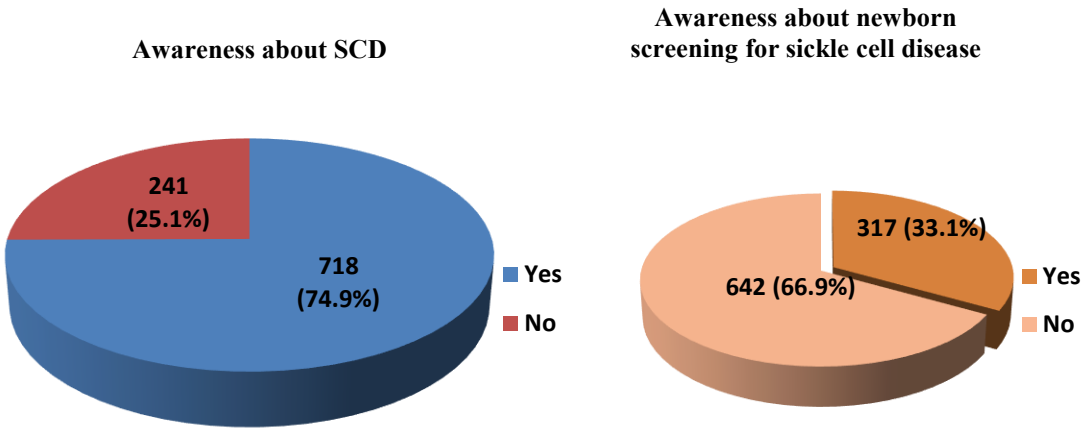

Figure 1: Awareness about sickle cell disease and newborn screening for sickle cell disease

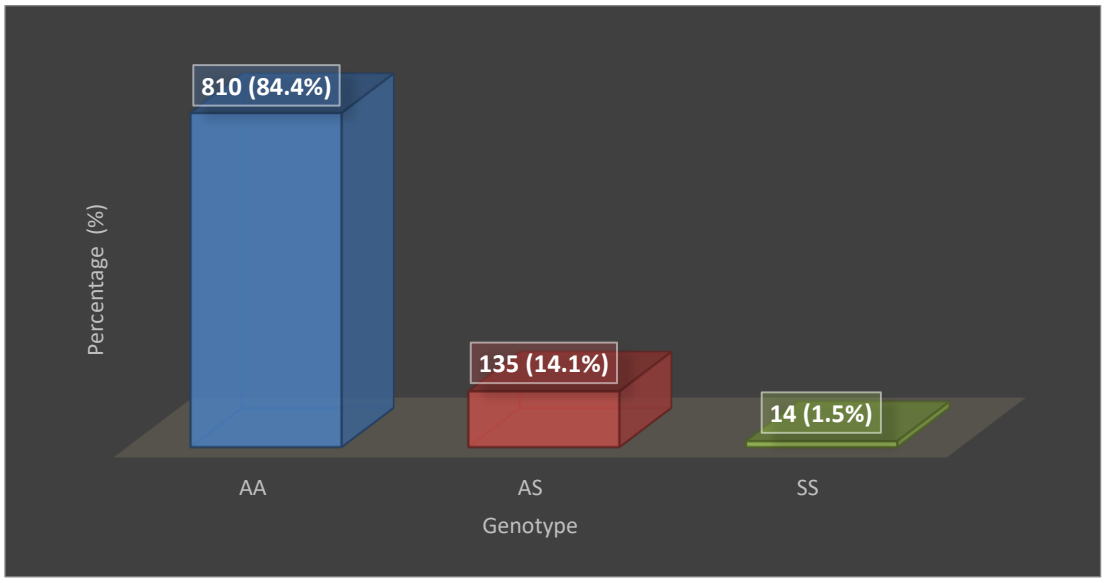

Figure 2: Bar chart showing the genotype of newborns

The majority of the newborns with sickle cell anaemia (n = 10) belonged to mothers who received no premarital counselling, but the relationship was not statistically significant. Most of the newborns with sickle cell anaemia were from mothers who knew about sickle cell disease (n = 10), but the relationship was also not statistically significant, as shown in Table III.

Discussion

The results of this study showed that awareness about Sickle Cell Disease among mothers was good, comparable to previous reports by Adigwe in Abuja.[28] Nnachi *et al.*,[29] in Abakaliki; Nnodu *et al.*,[30] from a nationwide survey; Katamea *et al.*,[31] from Congo. Knowing about sickle cell disease shows the level of mothers' awareness, and this could be due to continuous and ongoing education by both the government and civil society organisations.

Table IIa: Association between socio-demographic and sickle cell anaemia

Variables	Sickle cell disease		Statistics	p-value
	Sickle cell n = 14 n (%)	No sickle cell n = 945 n (%)		
Age (days)			2.22 [f]	0.750
1-7	7(1.9)	362(98.1)		
8-14	3(2.3)	126(97.7)		
15-21	1(1.6)	61(98.4)		
22-28	0(0.0)	30(100.0)		
29-36	0(0.0)	41(100.0)		
37-42	3(0.9)	325(99.1)		
Sex			0.32	0.571
Male	8(1.7)	468(93.2)		
Female	6(1.2)	477(98.8)		
Ethnicity			12.71[f]	0.049
Tiv	7(1.2)	591(98.8)		
Idoma	3(1.1)	275(98.9)		
Igede	2(10.5)	17(89.5)		
Yoruba	0(0.0)	5(100.0)		
Igbo	1(2.8)	35(97.2)		
Hausa	0(0.0)	3(100.0)		
Others	1(5.0)	19(95.0)		

f - Fisher's Exact Test

This level of awareness is needed to drive preventive strategies in reducing the incidence of sickle cell anaemia in the population. Mother's knowledge of their genotype was low (36.3%) but higher than the 3% previously reported by Ezenwosu *et al.* [21] in Benue State. Despite having good awareness about sickle cell disease, most mothers were not aware of their genotype, though the results from this study showed a significant increase from the 3% previously reported. This substantial increase could be due to awareness campaigns carried out in the hospitals and on the radio. Mothers who are aware of the disease but don't know their genotype represent a gap in testing that should be filled. The practice of premarital counselling was poor (35%), comparable with the report of Oluwole *et al.* [32] in Lagos and Qattan *et al.* [33] in Saudi Arabia and in keeping with the report of Dilli *et al.*[34] The poor practice of premarital screening for sickle cell disease, coupled with inadequate knowledge of mothers' genotype despite good awareness about sickle cell disease, reveals the gap between knowledge and practice, and this explains the continued high burden of sickle cell disease.[28,35] While measures are taken to address the gaps in premarital counselling, early screening in the newborn period offers another opportunity for early diagnosis with the potential for better outcomes through improved quality of care. Awareness of Newborn Screening was low (33.1%), similar to 22% reported by Nnachi *et al.* [18] in Abakaliki, and lower than 57.2% reported by Isa *et al.* [36] in Abuja. This disparity could be due to the cosmopolitan nature of Abuja, which has a more enlightened population with better awareness about sickle cell disease.

Table IIb: Association between socio-demographic and sickle cell anaemia

Variables	Sickle cell disease		Statistics	p-value
	Sickle cell n = 14 n (%)	No sickle cell n = 945 n (%)		
Mother's genotype status			0.26	0.607
Unknown	8 (1.1)	727 (98.9)		
Known	6 (2.7)	218 (97.3)		
Father's genotype status			0.15	0.692
Unknown	9 (1.1)	776 (98.9)		
Known	5 (2.9)	169 (97.1)		
Parity			3.66[f]	0.429
1	5 (1.4)	341 (98.6)		
2	6 (2.7)	213 (97.3)		
3	2 (1.3)	151 (98.7)		
4	1 (0.8)	128 (99.2)		
≥5	0 (0.0)	112 (100.0)		
Number of children alive			5.77[f]	0.163
1	5 (1.4)	348 (98.6)		
2	7 (3.1)	222 (96.9)		
3	2 (1.3)	152 (98.7)		
4	0 (0.0)	122 (100.0)		
≥5	0 (0.0)	101 (100.0)		
Place of birth			0.27	0.602
Hospital	13 (1.5)	835 (98.5)		
Home	1 (0.9)	110 (99.1)		

f - Fisher's Exact Test

Table III: Association between awareness of SCD, NBS and sickle cell anaemia

Variables	Sickle cell disease		Statistics	p-value
	Sickle cell n = 14 n (%)	No sickle cell n = 945 n (%)		
Genetic counseling				0.781[f]
Yes	4 (1.2)	332 (98.8)		
No	10 (1.6)	613 (98.4)		
Facility of screening			2.25[f]	0.310
BSUTH	6 (2.0)	291 (98.0)		
FUHSTHO	6 (1.7)	349 (98.3)		
GH Gboko	2 (0.7)	305 (99.3)		
Awareness of SCD				0.759[f]
Yes	10 (1.4)	708 (98.6)		
No	4 (1.7)	237 (98.3)		
Awareness of NBS				0.568[f]
Yes	3 (0.9)	314 (99.1)		
No	11 (1.7)	631 (98.3)		

f - Fisher's Exact Test

Several studies have been carried out about Newborn screening in Abuja, whereas this study is the first pilot study about newborn screening for sickle cell disease in Benue State. This shows that despite the provision of screening centres by the government, there is poor awareness, highlighting the need for increased awareness to drive the uptake of newborn screening. Acceptance of newborn screening was high, which was similar to previous reports by Odunvbun in Benin[37] Oluwole in Lagos,[38] Nnachi *et al.* in Ebonyi, [18] Nnodu *et al* in Abuja, [30] and Orimbo *et al.* in Kenya. [39] The high acceptance despite low awareness shows the good disposition of the people towards screening, and this can be utilised for the upscaling of newborn screening. Newborn screening showed SCA prevalence of 1.5% amongst neonates, compared to 2.8% by Odunvbun *et al.*,[37] in Benin, 1% by Nnodu *et al.*,[15] in Abuja, 1% by Nnachi in Ebonyi,[40] 1.3% by Ramatu *et al.*,[41] in Abuja and 1.7% by Galadanci *et al.*,[42] in Kano. The prevalence of sickle cell anaemia amongst the newborn population from this study was not quite different from previous documented results. However, the prevalence of 1.5% translates to a significant number in the general population, but this early identification presents an early opportunity for interventions that will lead to better outcomes.

Most newborns with sickle cell anaemia belonged to mothers who did not know their genotype. Even though the relationship was not statistically significant, it points to a significant reason behind the continued perpetuation of the sickle gene. This represents the gap that needs to be filled, as mothers who do not know their genotype, despite being aware of sickle cell disease, as reported by Ezenwosu *et al.*,[21] will end up marrying partners with similar genotypes, thereby providing an opportunity for the perpetuation of the sickle gene. Therefore, there is a need for continual education of mothers to improve their knowledge and hence influence marriage choices to drive the reduction of the incidence of sickle cell anaemia in the population.[35]

Limitation

Confirmation of haemoglobin genotype with HPLC or Isoelectric focusing following screening with the SickleScan test was not done.

Conclusion

Newborn screening using a point-of-care test was well accepted and can be easily incorporated into the immunisation schedule for mass screening. Early identification during immunization visits should be implemented because it allows for early initiation of care, potentially leading to better outcomes and quality of life.

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Authors' Contributions: MA conceived and designed the study, curated and analysed the data, and drafted the manuscript. MOA revised the draft for sound intellectual content. Both authors approved the final version of the manuscript.
Conflicts of Interest: None declared.
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