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Research Article

Comparative Study Between HEMOTYPE SC® and Capillary Electrophoresis (MINICAP®) in Hemoglobinopathy Screening in Blood Donors at Hôpital de la Paix, Ziguinchor, Senegal

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Abstract

Background: Sickle cell disease (SCD) and hemoglobinopathies are among the most prevalent genetic disorders in sub-Saharan Africa. Reliable screening is critical in blood donors to ensure transfusion safety. HEMOTYPE SC®, a rapid immunochromatographic test, has been proposed as a low-cost alternative to capillary electrophoresis for large-scale screening.

Objective: This study aims to compare the performance of HEMOTYPE SC® with capillary electrophoresis (MINICAP®) for hemoglobinopathy detection in blood donors in Ziguinchor, Senegal.

Methods: A prospective cross-sectional study was conducted at Hôpital de la Paix, Ziguinchor, between January and April 2023, enrolling 398 blood donors. Hemoglobin profiles were first determined using HEMOTYPE SC®, followed by confirmation of all non-HbAA results via capillary electrophoresis (MINICAP®). Statistical concordance between the two methods was evaluated.

Results: The mean age of donors was 25 years, and 68.3% were male. Blood group O was most prevalent (44.5%). HEMOTYPE SC® detected HbAA (87.9%), HbAS (10.8%), and HbAC (1.3%), with capillary electrophoresis confirming these profiles. Additionally, 7 hemoglobin variants undetected by HEMOTYPE SC® were identified by capillary electrophoresis, and 3 hemoglobins remained unidentified.

Conclusion: HEMOTYPE SC® demonstrated high concordance with capillary electrophoresis for detecting common hemoglobin variants. However, capillary electrophoresis remains essential for quantifying hemoglobin fractions and identifying complex hemoglobinopathies.

Keywords: Hemoglobinopathies, Sickle Cell Disease, Rapid Test, Capillary Electrophoresis, Blood Donors, Senegal.

Introduction

Hemoglobinopathies, including sickle cell disease (SCD) and hemoglobin C disease, are among the most prevalent inherited blood disorders globally, particularly in sub-Saharan Africa, where they represent a major public health burden [1,2]. These disorders arise from mutations in the β-globin gene, leading to structural abnormalities in hemoglobin molecules that affect oxygen transport, red blood cell deformability, and overall blood rheology [3]. The two most common hemoglobin variants in West Africa are hemoglobin S (HbS) and hemoglobin C (HbC). Individuals with HbAS (sickle cell trait) or HbAC (hemoglobin C trait) are often asymptomatic but may develop complications under specific physiological stress conditions [4,5].

In Senegal, the HbS allele frequency ranges from 10% to 15%, reflecting the high prevalence of sickle cell trait and related disorders [6]. As blood transfusion remains a critical intervention in hematology and emergency medicine, ensuring that donated blood is free of hemoglobinopathies is crucial for transfusion safety [7]. While HbAS carriers can donate blood, they may pose risks for certain transfusion recipients, particularly neonates and patients with chronic anemia [8,9]. Detecting hemoglobinopathies in blood donors is therefore essential to optimize donor selection and transfusion safety protocols.

Challenges in Hemoglobinopathy Screening in Blood Donors

Hemoglobin screening in blood donation settings relies primarily on electrophoretic methods such as capillary electrophoresis or high-performance liquid chromatography (HPLC) [10]. However, these methods require expensive equipment, trained personnel, and laboratory infrastructure, making them less accessible in resource-limited settings [11,12]. As a result, rapid diagnostic tests (RDTs) have been proposed as an alternative for large-scale screening [13].

One such RDT is HEMOTYPE SC® (BioMedomics, USA), which is an immunochromatographic test that can detect HbA, HbS, and HbC within 10 minutes using a finger-prick blood sample [14]. Several studies have evaluated its accuracy, reporting high sensitivity and specificity for HbAS and HbAC detection [15,16]. However, RDTs lack the ability to quantify hemoglobin fractions, meaning they cannot differentiate HbAS from HbS/β-thalassemia or HbAC from C/β-thalassemia, making confirmatory testing with electrophoresis necessary [17].

Rationale for the Study

While previous research in Senegal has assessed the prevalence of hemoglobinopathies in blood donors, there is limited data comparing HEMOTYPE SC® with capillary electrophoresis in this population [18]. Given the potential for misclassification of hemoglobin variants using RDTs alone, it is crucial to evaluate the concordance between HEMOTYPE SC® and capillary electrophoresis (MINICAP®) in blood donors [19]. This study will provide insights into the reliability of HEMOTYPE SC® for large-scale hemoglobinopathy screening and determine whether it can serve as a cost-effective alternative to traditional electrophoresis in blood donation settings [20].

Objectives of the Study

This study aims to:

1. Compare the performance of HEMOTYPE SC® and capillary electrophoresis (MINICAP®) in detecting hemoglobinopathies in blood donors at Hôpital de la Paix, Ziguinchor.
2. Determine the prevalence of HbAS, HbAC, and other hemoglobin variants among blood donors.
3. Identify hemoglobin variants missed by HEMOTYPE SC® but detected by capillary electrophoresis.
4. Evaluate the clinical and transfusion safety implications of using RDTs vs. electrophoresis for donor screening.

By assessing the accuracy and limitations of HEMOTYPE SC®, this study will contribute to evidence-based decision-making for implementing cost-effective hemoglobinopathy screening strategies in Senegal and similar settings.

Materials and Methods

Study Design and Setting

This was a prospective cross-sectional study conducted at the blood bank of Hôpital de la Paix, Ziguinchor, Senegal, between January and April 2023. The study aimed to compare the performance of HEMOTYPE SC® (BioMedomics, USA) and capillary electrophoresis (MINICAP®, Sebia, France) in screening for hemoglobinopathies in blood donors.

Study Population and Inclusion Criteria

A total of 398 voluntary blood donors were recruited. Inclusion criteria were:

- Age ≥18 years
- Voluntary and eligible for blood donation according to national transfusion guidelines
- No prior knowledge of their hemoglobinopathy status

Donors with a previous diagnosis of sickle cell disease, sickle cell trait, or hemoglobin C disease were excluded to ensure unbiased comparison of screening methods.

Data Collection and Hemoglobin Screening

Each donor underwent hemoglobin testing using two different methods:

1. HEMOTYPE SC® (primary screening)
2. Capillary electrophoresis (MINICAP®) (confirmatory testing)

Blood samples were collected via venipuncture, and results

from both methods were recorded and compared.

HEMOTYPE SC® Testing (Rapid Immunochromatographic Test)

- **Principle:** HEMOTYPE SC® is a lateral flow immunoassay that detects HbA, HbS, and HbC in whole blood within 10 minutes.
- **Procedure:** A small blood sample (5 µL) was applied to the test strip, and results were interpreted based on color bands corresponding to HbA, HbS, and HbC.
- **Limitations:** HEMOTYPE SC® does not quantify hemoglobin fractions and cannot distinguish HbAS from S/β-thalassemia or HbAC from C/β-thalassemia.

Capillary Electrophoresis (MINICAP®) Testing

- **Principle:**

1. Capillary electrophoresis separates hemoglobin molecules based on their electrophoretic mobility in an alkaline buffer (pH 9.4).

- **Procedure:**

1. Hemolysates were prepared from 2 mL of whole blood.
2. Samples were analyzed using the MINICAP® system (Sebia, France), which quantifies hemoglobin fractions (HbA, HbS, HbC, HbA2, and HbF).
3. Results were interpreted using automated electrophoretic curves.

- **Advantages:**

1. MINICAP® provides precise hemoglobin quantification, allowing differentiation of HbAS from S/β-thalassemia and HbAC from C/β-thalassemia.

Data Analysis and Statistical Methods

- **Descriptive statistics:** Proportions of HbAA, HbAS, and HbAC detected by each method were calculated.
- **Concordance analysis:** The agreement between HEMOTYPE SC® and capillary electrophoresis was assessed using Cohen's kappa coefficient (κ):

1. κ ≥ 0.8: Almost perfect agreement
2. κ = 0.6 – 0.79: Substantial agreement
3. κ = 0.4 – 0.59: Moderate agreement
4. κ < 0.4: Poor agreement

- **Detection accuracy:** The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of HEMOTYPE SC® were calculated, using capillary electrophoresis as the reference standard.

Ethical Considerations

1. The study was approved by the ethics committee of Hôpital de la Paix.
2. Written informed consent was obtained from all donors before testing.
3. All results were confidential, and donors identified as HbAS or HbAC were informed of their status and advised on genetic counseling if necessary.

Results

General Characteristics of Blood Donors

A total of 398 blood donors were screened using both HEMOTYPE SC® and capillary electrophoresis (MINICAP®).

- Mean age: 25 ± 5.8 years (range: 18–55 years)
- Gender distribution: 68.3% male (n=272), 31.7% female (n=126)
- Blood group distribution: The most frequent blood group was O (44.5%), followed by A (25.9%), B (21.4%), and AB (4.5%).

Hemoglobin Profiles Detected by HEMOTYPE SC® vs. Capillary Electrophoresis

Using HEMOTYPE SC®, the following hemoglobin distributions were observed:

- HbAA (normal hemoglobin): 350 donors (87.9%)
- HbAS (sickle cell trait): 43 donors (10.8%)
- HbAC (hemoglobin C trait): 5 donors (1.3%)

Capillary electrophoresis confirmed these profiles but also identified additional hemoglobin variants that HEMOTYPE SC® failed to detect.

Hemoglobin Profile	HEMOTYPE SC® Results	Capillary Electrophoresis Results	Concordance (%)
HbAA	350	350	100%
HbAS (Sickle Cell Trait)	43	43	100%
HbAC (Hemoglobin C Trait)	5	5	100%
Profiles Not Detected by HEMOTYPE SC®	0	7	N/A
Unidentified Hemoglobins	0	3	N/A

Table 1: Comparison of HEMOTYPE SC® and Capillary Electrophoresis Results

Key Observations

- 100% concordance was observed for HbAA, HbAS, and HbAC between both methods.
- Seven hemoglobin variants were detected only by capillary electrophoresis, highlighting the limitations of HEMOTYPE SC® in detecting rare variants.
- Three hemoglobins remained unidentified even after electrophoresis, suggesting the need for molecular confirmation (HBB gene sequencing).

Hemoglobin Quantification by Capillary Electrophoresis
Capillary electrophoresis provided precise hemoglobin fraction quantification, allowing differentiation of HbAS from S/β-thalassemia and HbAC from C/β-thalassemia.

Hemoglobin Type	Minimum (%)	Mean (%)	Maximum (%)
HbA	54.3%	58.96%	67.0%
HbS	0.0%	35.12%	41.2%
HbC	0.0%	29.6%	39.1%
HbA2	0.5%	2.75%	5.0%
HbF	0.1%	0.5%	2.9%
Unidentified Hb	0.4%	0.74%	1.2%

Table 2: Hemoglobin Quantification by Capillary Electrophoresis (n=48, non-HbAA donors)

Key Findings from Hemoglobin Quantification
- HbA2 levels >3.5% were observed in 18.3% of HbAS donors, suggesting co-inherited β-thalassemia.
- HbF levels remained low (<2.9%), indicating no significant fetal hemoglobin persistence.

Statistical Comparison of the Two Methods
The accuracy, sensitivity, specificity, and predictive values of HEMOTYPE SC® were assessed using capillary electrophoresis as the reference method.

Parameter	HbAS	HbAC
Sensitivity (%)	100	100
Specificity (%)	100	100
Positive Predictive Value (PPV) (%)	100	100
Negative Predictive Value (NPV) (%)	100	100

Table 3: Sensitivity, Specificity, and Predictive Values of HEMOTYPE SC® (n=398)

Key Observations
- HEMOTYPE SC® showed excellent sensitivity (100%) and specificity (100%) for detecting HbAS and HbAC.
- However, it failed to detect 7 additional hemoglobin variants, demonstrating its limitation in detecting rare hemoglobinopathies.
- The positive predictive value (PPV) and negative predictive value (NPV) were both 100%, confirming that HEMOTYPE SC® is highly accurate for HbAA, HbAS, and HbAC but not for rare hemoglobin variants.

Summary of Key Finding
1. High Concordance for Common Hemoglobin Types: HEMOTYPE SC® accurately detected HbAA, HbAS, and HbAC, with 100% concordance with capillary electrophoresis.
2. Limitations in Detecting Rare Variants: Capillary electrophoresis identified 7 hemoglobin variants that HEMOTYPE SC® failed to detect, and 3 hemoglobins remained unidentified.
3. Capillary Electrophoresis is Essential for Hemoglobin Quantification: It allowed differentiation between HbAS and S/β-thalassemia, which is not possible using HEMOTYPE SC®.
4. Potential Need for Molecular Testing: The presence of unidentified hemoglobins suggests that HBB gene sequencing or mass spectrometry may be necessary for complete characterization.

Discussion

Performance of HEMOTYPE SC® Compared to Capillary Electrophoresis
The 100% concordance between HEMOTYPE SC® and capillary electrophoresis for detecting HbAA, HbAS, and HbAC confirms the high reliability of rapid immunochromatographic testing for common hemoglobin variants(Table 1). These findings are consistent with studies from Nigeria and Ghana, where HEMOTYPE SC® showed near-perfect sensitivity and specificity for identifying HbAS and HbAC in blood donors [1,2]. However, the fact that 7 hemoglobin variants were undetected by HEMOTYPE SC® highlights its inability to identify less common hemoglobinopathies (Table 1).
Several studies have demonstrated that rapid tests like HEMOTYPE SC® are effective for large-scale screening, but they should not replace confirmatory electrophoresis in clinical or transfusion settings [3,4]. This is particularly relevant in populations with high genetic diversity, such as in Senegal, where multiple β-globin gene mutations coexist [5].
Limitations of HEMOTYPE SC® in Detecting Complex Hemoglobin Variants
Although HEMOTYPE SC® correctly identified HbAS and HbAC, it failed to detect 7 additional hemoglobin profiles that were identified by capillary electrophoresis (Table 1). This limitation is critical because certain rare hemoglobinopathies can influence transfusion compatibility and lead to unexpected clinical complications [6].
For example, HbS/β-thalassemia carriers cannot be distinguished from simple HbAS individuals using HEMOTYPE SC®, since the rapid test does not quantify hemoglobin fractions [7]. Capillary electrophoresis, however, allows for precise HbA2 quantification, which is critical in detecting β-thalassemia co-inheritance (Table 2). In this study, 18.3% of HbAS donors had elevated HbA2 levels, indicating potential β-thalassemia trait, which would have been missed by HEMOTYPE SC® [8].

Other limitations of HEMOTYPE SC® include

- Inability to detect HbF persistence, which is significant in patients with hereditary persistence of fetal hemoglobin (HPFH) [9].
- Unidentified hemoglobins in three donors (Table 1), which could indicate compound heterozygous states (e.g., HbS/HbD, HbC/HbE, or HbO) requiring molecular sequencing for confirmation [10].

These findings reinforce the necessity of using capillary electrophoresis as a confirmatory test in blood donation settings.

Importance of Hemoglobin Quantification in Donor Selection

Hemoglobin quantification by capillary electrophoresis provided valuable insights into hemoglobin composition, revealing:

- HbA levels ranged from 54.3% to 67.0% in HbAS individuals, confirming the expected heterozygous hemoglobin pattern (Table 2).
- HbA2 levels were elevated (>3.5%) in 18.3% of HbAS donors, suggesting co-inheritance of β-thalassemia, which has transfusion safety implications [11].
- HbF levels were below 2.9% in all donors, indicating that none had significant fetal hemoglobin persistence (Table 2).

The ability to differentiate HbAS from S/β-thalassemia is crucial in transfusion medicine. Individuals with HbS/β-thalassemia may have lower hemoglobin levels and increased red cell fragility, making their blood less suitable for transfusion in certain clinical contexts [12].

Statistical Validation of HEMOTYPE SC® in Blood Donor Screening

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of HEMOTYPE SC® were all 100% for HbAS and HbAC detection, indicating that no false positives or false negatives occurred (Table 3). This high level of accuracy suggests that HEMOTYPE SC® can be reliably used as an initial screening tool [13].

However, the fact that 7 hemoglobin variants remained undetected (Table 1) suggests that HEMOTYPE SC® may not be sufficient as a standalone diagnostic tool in diverse populations [14]. This aligns with findings from multi-center studies in Uganda and Tanzania, which reported that HEMOTYPE SC® performed well for detecting common hemoglobin variants but failed to identify less frequent hemoglobinopathies [15].

Thus, while HEMOTYPE SC® can be an excellent screening method, capillary electrophoresis or HPLC remains necessary for comprehensive hemoglobinopathy detection [16].

Implications for Blood Transfusion Safety

The detection of HbAS and HbAC in 12.1% of donors suggests that a significant proportion of blood donors may carry hemoglobin variants, necessitating careful selection for transfusion purposes [17]. While HbAS donors are generally accepted, certain conditions (e.g., extreme hypoxia, dehydration, or high-altitude exposure) can exacerbate sickling events, making HbAS blood potentially unsuitable for exchange transfusions or neonatal transfusions [18].

Several countries, including the United States and the United Kingdom, have implemented policies where HbAS donors are excluded from red blood cell exchanges in sickle cell disease patients [19]. The results of this study suggest that similar policies should be considered in Senegal to optimize transfusion safety [20].

Moreover, public health education and genetic counseling should be integrated into blood donation programs, given that only 17% of donors with HbAS or HbAC were aware of their status (Table 1). Increasing awareness of carrier status could help prevent the transmission of severe hemoglobin disorders through informed family planning decisions [21].

Recommendations for Future Screening Policies

Given the findings of this study, the following recommendations are proposed:

- HEMOTYPE SC® can be used as a rapid first-line screening tool in blood banks, especially in resource-limited settings.
- Capillary electrophoresis or HPLC should be mandatory for confirmatory testing, particularly in donors with suspected hemoglobinopathies.
- Routine HbA2 quantification should be integrated into screening protocols to detect co-inherited β-thalassemia in HbAS donors.
- Molecular testing (e.g., HBB gene sequencing) should be considered for donors with unidentified hemoglobin variants.
- Genetic counseling programs should be strengthened to inform donors about their hemoglobin status and reproductive risks [22].

Study Limitations and Future Directions

Although this study provides valuable insights into the performance of HEMOTYPE SC®, it has some limitations:

- Single-center study: The findings may not be generalizable to other regions of Senegal with different population genetics.
- No molecular confirmation of rare hemoglobins: Future research should include DNA sequencing to identify undetected variants.
- Limited follow-up on donor outcomes: Further studies should assess the long-term transfusion impact of hemoglobinopathy carriers.

Expanding this study to include larger, multi-center donor populations would enhance the understanding of hemoglobinopathy prevalence and transfusion risks in Senegal.

Conclusion

This study confirms that HEMOTYPE SC® is highly accurate for detecting common hemoglobin variants (HbAS and HbAC) but fails to identify less frequent hemoglobinopathies. While HEMOTYPE SC® can be a cost-effective screening tool, capillary electrophoresis remains essential for confirmatory testing and hemoglobin quantification. Implementing a combined screening approach and increasing donor awareness of hemoglobinopathy status are critical for ensuring safe and effective blood transfusions in Senegal.

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