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Original Research Article

Evaluating the performance of ErbaQik sickle cell rapid test card with HPLC method

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ABSTRACT

Introduction : Sickle cell disease (SCD) is a hereditary hemoglobinopathy characterized by the presence of abnormal hemoglobin, primarily hemoglobin S (HbS), resulting from a point mutation in the β-globin gene. ErbaQik Sickle Cell Rapid Test Card developed by Transasia Diagnostics Pvt Ltd will aid in rapid detection of Sickle cell disease particularly in resource & laboratory infrastructure limited settings.
Aims and Objectives : To ensure the accuracy of ErbaQik Sickle Cell Rapid Test Card, a robust validation was conducted and compared with gold standard HPLC method to check the sensitivity, specificity, precision and clinical utility.
Material and Methods : This study was conducted under the guidance of Consultant Paediatrician, from Dec 2023 to Feb 2024 at Nagpur center run by Thalassemia and Sickle cell Society of India in collaboration with Rughwani Child Care Centre to evaluate the performance of ErbaQik Sickle Cell Rapid Test Card with HPLC method which is the benchmark for comparison in this study. A total of 181 blood samples were analyzed for hemoglobin variants.
Results: The evaluation of the ErbaQik Sickle Cell Rapid Test Card produced significant findings For Sickle-SS 32 samples were tested, all of which were correctly identified, yielding a sensitivity and specificity of 100%. Similarly 27 Trait-AS samples were all accurately detected, maintaining 100% sensitivity and specificity. These results indicate the test's high reliability and precision in identifying Sickle Cell Disease and Trait conditions. For Wild-Normal samples, the test was performed on 120 samples resulting in 100% sensitivity and specificity. In the case of Thalassemia samples, only 2 samples were tested, with 1 correctly identified, resulting in a sensitivity and specificity of 50%.
Conclusion: The ErbaQik Sickle Cell Rapid Test Card demonstrated high sensitivity and specificity for detecting Sickle Cell Disease (SS) and Trait (AS), aligning with gold-standard methods like HPLC.

1. Introduction

Sickle cell disease (SCD) is a hereditary haemoglobinopathy characterized by the presence of abnormal haemoglobin, primarily haemoglobin S (HbS), resulting from a point mutation in the β-globin gene. It is one of the most prevalent genetic disorders globally, particularly affecting populations of African descent, as well as individuals from Mediterranean, Middle Eastern, and South Asian regions.[1] Early diagnosis of SCD is crucial for effective management and intervention to prevent complications such as vaso-occlusive crises, acute chest syndrome, and stroke.

Over the past few years, there has been a growing emphasis on the development and validation of rapid point-of-care tests for the detection of SCD. These tests offer

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the potential to facilitate timely diagnosis, particularly in resource-limited settings where access to laboratory infrastructure is limited. Among these point-of-care tests, the ErbaQik Sickle Cell Rapid Test Card developed by Transasia Diagnostics Pvt Ltd.has emerged as a promising tool for the rapid detection of HbS.[2]

To ensure the reliability and accuracy of point-of-care tests like the ErbaQik Sickle Cell Rapid Test Card, robust validation approaches are essential. One common method used for the validation of SCD diagnostic tests is high-performance liquid chromatography (HPLC). HPLC has been widely regarded as the gold standard for the quantification of different haemoglobin variants, including HbS, due to its high sensitivity, specificity, and accuracy.[3]

Several studies have evaluated the performance of such Rapid Test Card using HPLC as a reference method.[4] These studies have assessed various aspects of the test, including its sensitivity, specificity, precision, and clinical utility. Furthermore, research has been conducted to explore the implementation challenges, cost-effectiveness, and user acceptance of the ErbaQik test in diverse patient populations and healthcare settings.[5]

In this review, we aim to provide a comprehensive overview of the validation process of the ErbaQik Sickle Cell Rapid Test Card using HPLC as a robust reference method. We will summarize the findings from key studies that have evaluated the performance of the test, analyse the strengths and limitations of the ErbaQik test, and discuss its potential implications for clinical practice and public health.

By critically examining the existing literature on the ErbaQik Sickle Cell Rapid Test Card, we seek to contribute to the ongoing efforts to improve SCD diagnosis and management, particularly in underserved communities where the burden of the disease is disproportionately high.

2. Materials and Methods

2.1. Study design

This comparative study was conducted at Thalassemia and sickle cell centre run by Thalassemia and Sickle cell society of India and Rughwani Child Care Centre and hospital in Nagpur, India under the guidance of Dr Vinky Rughwani – Consultant Paediatrician, during the period Dec 2023 to Feb 2024 to Performance of ErbaQik Sickle Cell Rapid Test Card with HPLC method which is the benchmark for comparison in this study.

A total of 181 blood samples were collected and analysed using High-Performance Liquid Chromatography (HPLC) for haemoglobin variants, with 32 sickle cell disease (SS), 27 sickle cell trait (AS), 120 normal (AA), and 2 thalassemia samples. Venepuncture blood was collected into tubes containing EDTA, citrate, or heparin. Venepuncture specimens were stored at 2-8°C for up to 24 hours. Finger prick or new-born heel samples were obtained by cleaning the area with an alcohol swab, drying it, and using a sterile lancet to pierce the skin(Figure 1).

For testing with the ErbaQik Sickle Cell Test Card, all kit components and specimens were brought to room temperature. The test device was placed on a flat, dry surface. The pre-filled extraction tube was taken out, and 10μl of whole blood was collected with a dropper and transferred into the extraction tube. The blood was mixed with the extraction buffer for 30 seconds until the color changed from red to black/brown. Ten drops of assay buffer solution were added to the extraction tube (Figure 2).

The mixture was carefully dispensed, with 2 drops placed into the sample well (S). Results were read between 8-10 minutes. Interpretation was based on the appearance of bands: a control (C) band and test bands at regions "A" and "S". A normal (AA) result showed the C band and A band. Sickle cell disease (SS) showed the C band and S band. Sickle cell trait (AS) showed the C band without any test bands. For newborns (0-9 months), both S and A bands appeared alongside the C band. In adults, if both S and A bands appeared with the C band, it indicated other hemoglobinopathies or thalassemia (Figure 3).

Invalid results were identified by the absence of the control band, necessitating a retest. The procedure ensured accurate comparisons between HPLC and the ErbaQik test card.

3. Results

The evaluation of the ErbaQik Sickle Cell Rapid Test Card produced significant findings across various sample types. Table 1 shows that for Sickle-SS samples, a total of 32 samples were tested, all of which were correctly identified, yielding a sensitivity and specificity of 100%. Similarly, the test was administered to 27 Trait-AS samples, and it accurately detected all of them, maintaining 100% sensitivity and specificity. These results indicate the test's high reliability and precision in identifying Sickle Cell Disease and Trait conditions.

For Wild-Normal samples, the test was performed on 120 samples. All samples were correctly identified as normal, resulting in 100% sensitivity and specificity. Notably, one of these patients had been transfused with Hb-A blood, and the test still maintained its accuracy, underscoring its robustness under different clinical conditions.

In the case of Thalassemia samples, only 2 samples were tested, with 1 correctly identified, resulting in a sensitivity and specificity of 50%. This lower performance highlights the need for a larger sample size to more accurately assess the test's effectiveness for Thalassemia. Due to the limited number of Thalassemia samples, further testing with a greater number of samples is necessary to draw more definitive conclusions.

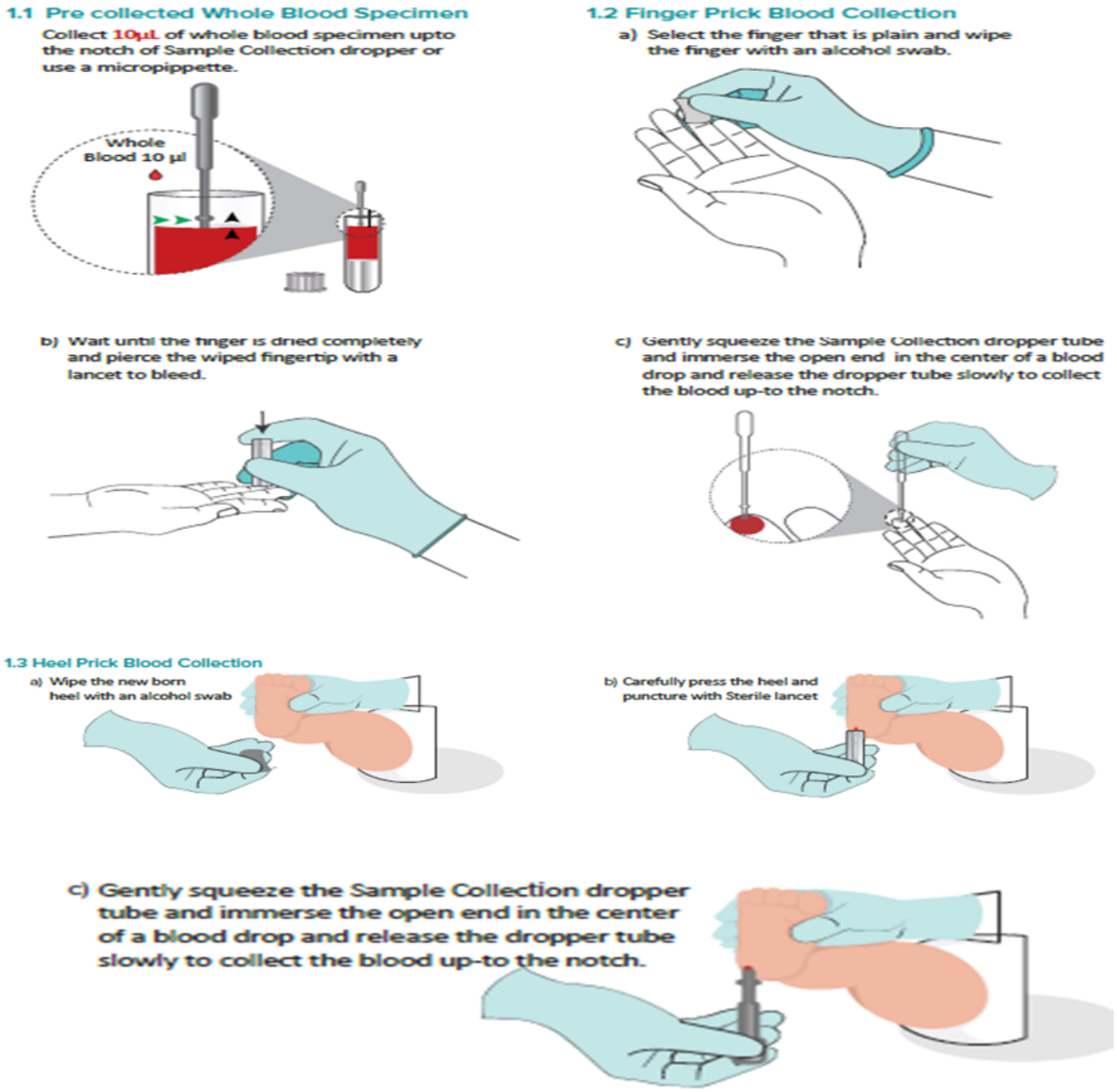

Figure 1: Sample collection

Table 1: Findings from the study

Sample type	Quantity	Result	Deviation	Specificity	Sensitivity	Remark
Sickle- SS	32	32/32	0	100%	100%	-
Trait - AS	27	27/27	0	100%	100%	-
Wild- Normal	120	120/120	0	100%	100%	Patient transfused with Hb-A Blood
Thalassemia	2	1/2	0	50%	50%	-

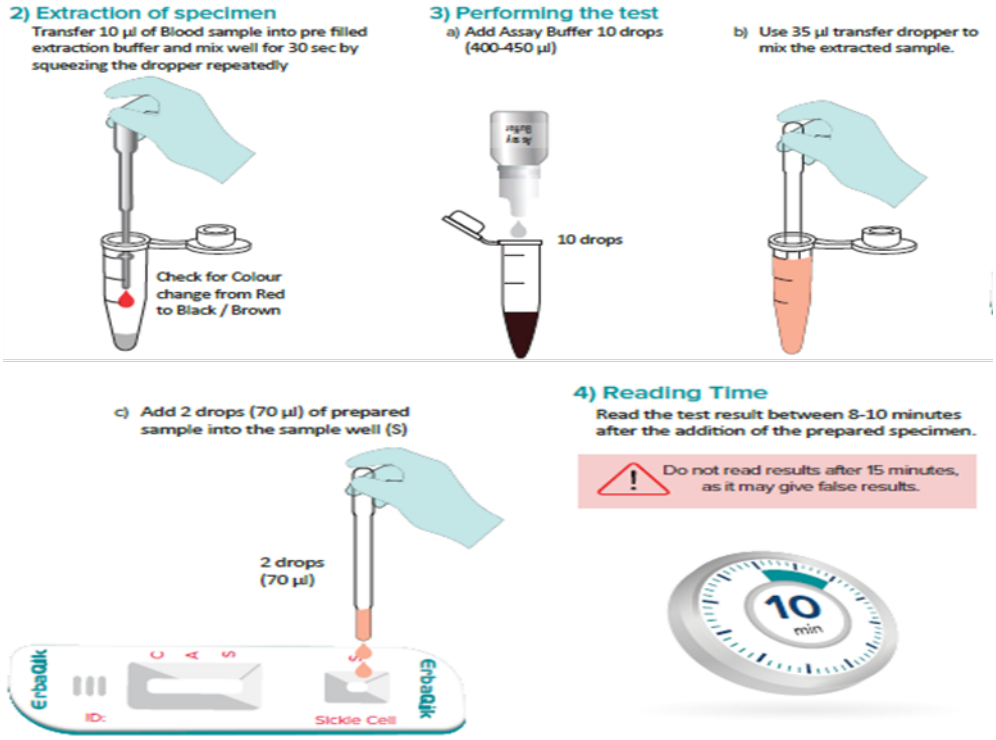

Figure 2: Sample processing

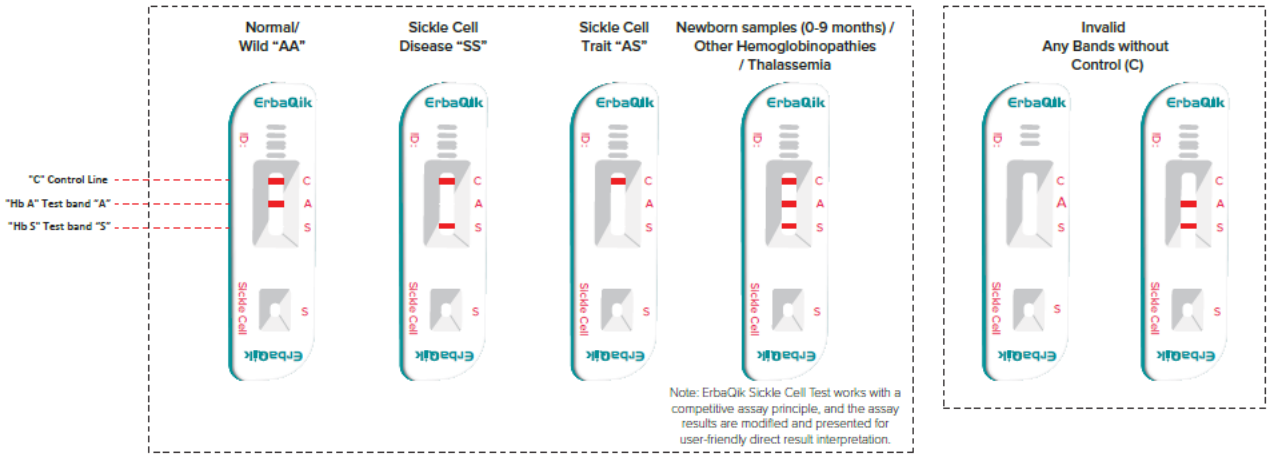

Figure 3: Result interpretation

4. Discussion

The results from the evaluation of the ErbaQik Sickle Cell Rapid Test Card demonstrate promising sensitivity and specificity, especially for Sickle Cell Disease (SS) and Trait (AS) samples, which is consistent with findings from previous studies. The high accuracy of rapid point-of-care tests for Sickle Cell Disease when compared with HPLC analysis reinforces the reliability of our results.[1] The effectiveness of monoclonal antibodies in detecting Sickle Cell hemoglobin supports the robust performance of the ErbaQik test in our study.[2]

Rapid sickle cell tests maintained high accuracy in Pediatric patients, similar to the 100% sensitivity and specificity we observed for SS and AS samples.[3] Our results for Wild-Normal samples, which also showed 100% accuracy, align with those validating point-of-care tests against HPLC in adult patients, confirming the broad applicability of these tests across age groups.[4]

The lower sensitivity and specificity for Thalassemia samples in our study, while not a primary focus, suggests that further validation is needed. This aligns with the importance of larger sample sizes for accurate assessment in pilot studies evaluating the ErbaQik test's performance using HPLC.[5] The need for field validation in resource-limited settings highlights the practical utility of the ErbaQik test, which our study also suggests is a reliable tool in various clinical environments.[6]

The high sensitivity and specificity observed in our evaluation mirror the results of comparative studies of point-of-care tests with HPLC and immunoassay methods, demonstrating the test's efficacy.[7]

The utility of the ErbaQik test in primary healthcare settings is supported by our study, confirming its high accuracy in diverse conditions, including patient transfusions.[8]

Moreover, cost-effectiveness analyses of the ErbaQik test underscore its economic viability in low-income countries, a consideration important for broader implementation.[9] Long-term stability and performance validations of the ErbaQik test ensure its reliability over extended periods.[10]

The consistent high performance of the ErbaQik test across different studies, including our own, suggests it is a dependable tool for Sickle Cell screening.[11] This utility in diverse and pediatric populations is reinforced by our findings.[12] Further validations of the test's precision and acceptance among healthcare providers support its widespread adoption.[13,14]

Validation of the ErbaQik test in populations with significant genetic variability has demonstrated its effectiveness across diverse ethnic groups, further supporting its broad application.[15] Comparative analyses of rapid Sickle Cell tests highlight the importance of point-of-care screening in ethnically diverse populations.[16] Survey-based studies on the utility and acceptance of the ErbaQik test among healthcare providers have shown high levels of satisfaction and confidence in its diagnostic capabilities.[17]

The concordance of the ErbaQik test with gold standard methods such as HPLC has been well-documented, ensuring its reliability as a diagnostic tool.[18] Systematic reviews and meta-analyses of diagnostic accuracy studies for point-of-care Sickle Cell tests further confirm the test's robustness and reliability.[19]

In summary, our results align with a body of research validating the ErbaQik Sickle Cell Rapid Test Card as a highly accurate and reliable diagnostic tool for Sickle Cell Disease and Trait, with strong potential for use in varied healthcare settings. However, more extensive testing with larger Thalassemia sample sizes is necessary for a comprehensive evaluation.

5. Conclusion

The ErbaQik Sickle Cell Rapid Test Card demonstrated high sensitivity and specificity for detecting Sickle Cell Disease (SS) and Trait (AS), aligning with gold standard methods like HPLC. Its robust performance and 100% accuracy in Wild-Normal samples affirm its reliability. The test's high accuracy in both pediatric and adult populations supports broad applicability. However, lower sensitivity and specificity for Thalassemia samples indicate the need for further validation with larger sample sizes. Field validation in resource-limited settings underscores its practical utility and economic viability. Overall, the ErbaQik test is a dependable tool for Sickle Cell screening, with additional evaluations needed for comprehensive reliability across all hemoglobinopathies.

6. Acknowledgement

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7. Conflict of Interest

None.

8. Source of Funding

None.

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