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ORIGINAL ARTICLE

Evaluating the Accuracy of Hepatitis C Virus Rapid Test Kits versus Polymerase Chain Reaction in Screening Prospective Blood Donors in Rivers State, Nigeria

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ABSTRACT

Background: Rapid Diagnostic Tests can provide a good alternative for screening for hepatitis C virus in resource-poor settings. Rapid diagnostic test kits are cheaper, quicker, and require less skill and instrumentation. Method: A cross-sectional study design was used for this study. 200 potential blood donors were recruited from Rivers State University Teaching Hospitals, University of Port Harcourt Teaching Hospital, Rukpoku, Ozuoba, and Iriebe Model Primary Health Care Centres in Port Harcourt. Their samples were collected and serologically tested using four different rapid diagnostic test kits for the hepatitis C virus. One hundred and fifty (150) samples had discrepant results with the four different rapid diagnostic tests (ROSTEC, Skytec, Tell, and LabACON), and 50 were negative with the four different rapid diagnostic test kits, and they served as control. The 150 samples that showed discrepant results were sent for confirmation using a polymerase chain reaction. The study aimed to evaluate the accuracy of hepatitis c virus rapid test kits versus polymerase chain reaction (real-time polymerase chain reaction) in screening potential blood donors in rivers state.

Results: The comparison of performance characteristics of rapid diagnostic kits used for the screening of hepatitis C among prospective blood donors shows that the different kits used had different sensitivity, specificity, and accuracy. The Skytech rapid diagnostic kit had a sensitivity of 57%, specificity of 50%, and accuracy of 53%. There was a positive predictive value of 36 and a negative predictive value of 71. The Rostec rapid diagnostic kit had a sensitivity, specificity, and accuracy of 73%, 84%, and 77%, respectively, with a positive and negative predictive value of 35 and 72. The Tell rapid diagnostic kit had a sensitivity of 92%, a specificity and accuracy of 79% and 71%. There was a positive predictive value of 75 and a negative predictive value of 81. The Lab Acon rapid diagnostic kit had a sensitivity of 88%, a specificity of 61%, and an accuracy of 93%. The Lab Acon rapid diagnostic kit had a positive

predictive value of 70 and a negative predictive value of 78. The Tell rapid diagnostic kit had the highest sensitivity among the four kits, with the Skytech rapid diagnostic test kit having the lowest sensitivity. The specificity for the four different kits was Rostec> Tell > Lab Acon > Skytec.

Conclusion: The Rostec diagnostic test kit had the highest specificity but the third lowest specificity. The most accurate diagnostic test kit among the four in the study was the Lab Acon diagnostic test kit, and the least was the Skytech rapid diagnostic test kit. Therefore, rapid diagnostic test kits are reliable and feasible for screening hepatitis C virus in resource-poor settings.

Keywords: Accuracy, Hepatitis C Virus, Test Kits, Blood Donors

INTRODUCTION

Blood transfusion is one of the routine therapeutic interventions in hospitals that play a key part in patient management (1). The World Health Organization (WHO), to assure the quality and safety of transfused blood, recommends screening of donors and donated blood and blood components for a minimum of the major transfusion-transmittable infections, including human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) and syphilis (2). However, despite the screening process, blood transfusion is related to several transfusion-related infections and hepatitis C viral infection is one of the most common causes of transfusion-related hepatitis (3).

The hepatitis C virus (HCV) was first diagnosed in 1989, and since then it has become a significant public health problem. However, in 2023, the World Health Organization estimated approximately 50 million people worldwide living with chronic hepatitis C virus (HCV) infection, with about 1 million new infections occurring annually, this represent a significant decrease from previous years, indicating progress in combating the disease (4). Also, according to World Health Organization (WHO), annually there are about 3-4 million new cases of persons infected with the virus (5; 6). The prevalence of HCV among blood donors varies from 0.4 to 19.2%. The estimated chance of HCV transmission during blood transfuses ranges from 0.10 to 2.33 per million units transfused (7; 8). Hepatitis C virus causes acute hepatitis which is mostly subclinical, but which gradually evolves into chronic hepatitis in about 80% of those infected (9).

Hepatitis C virus infection is estimated to account for over 400,000 deaths each year (10), with most people being unaware that they are infected, and this is because the "serologic window" between HCV infection and the detection of specific antibodies varies from one person to another (11), hence HCV infection is often referred to as the "silent pandemic" (12; 13). In many resource-limited settings, HCV often remains undiagnosed until a patient presents at a health-care facility with cirrhosis or hepatocellular carcinoma (14).

Hepatitis C virus is a small, enveloped, positive single-stranded RNA virus that belongs to the *Flaviviridae* family, genus *Hepacivirus* (15; 16). It is the most common blood-borne pathogen and a leading cause of morbidity and mortality as it is a major cause of liver diseases including liver cirrhosis and hepatocellular carcinoma (17). On the basis of nucleotide variation HCV is divided into six major genotypes and more than 80 subtypes (18).

All currently recognized HCV genotypes are hepatotropic and pathogenic (19). However, it has been suggested that different genotypes do vary in their infectivity and pathogenicity, thereby influencing the rate of progression to cirrhosis and the risk of Hepatocellular Carcinoma (HCC) (20).

Hepatitis C virus screening has several potential benefits including the detection of the HCV infection early so that antiviral treatment can be commenced earlier in the course of the disease which is more effective than starting at a later stage (21). Further, early detection together with counseling and lifestyle modifications may reduce the risk of transmission of HCV infection to other people. The optimal approach to screen for HCV is to test the individuals having risk factors for exposure to the virus (22). And it has been found that blood donors, particularly those that rely on blood donation as a source of income have a very high rate of HCV infection (23).

Screening tests for blood donations are based upon sensitivity, cost-effectiveness and their suitability for high-throughput testing (24). Various types of assays have been developed for use in blood screening over the past three decades. The assays most commonly in use are designed to detect antibodies, antigens or the nucleic acid of the infectious agent. However, not all assays are suitable in all situations and each assay has its limitations which need to be understood and taken into consideration when selecting assays (25;24).

Virological diagnosis of HCV infection is based on two categories of laboratory tests, namely serologic assays detecting specific antibody to HCV (anti-HCV) (indirect tests) and assays that can detect, quantify, or characterize the components of HCV viral particles, such as HCV RNA and core antigen (direct tests) (11). Both the direct and indirect virological tests play an important role in the diagnosis of the infection and therapeutic decision-making (11).

There is a global need to expand HCV diagnostic testing (26). The traditional approach to diagnosis of HCV requires an initial antibody (Ab) test to know if a person has become exposed to the viral infection, followed by a confirmation of ongoing viremia, usually using a polymerase chain reaction (PCR)–based assay to quantify the level of HCV RNA in the blood (27). Individuals who test Ab positive but HCV RNA negative have either spontaneously cleared the infection (usually within 6-12 months of initial infection) or been successfully treated. Other much less common possibilities are false-positive Ab tests or acute infection during which the HCV RNA can be transiently undetectable. Current antibody and HCV RNA assays have very high sensitivity and specificity, making false-positive and false-negative results rare occurrences (27).

The importance of low-cost molecular diagnostic assays is especially important for the developing nations who are economically backwards, as they are already burdened with increasing number of hepatitis C patients (28). The advent of molecular diagnostic approaches has allowed for the development of nucleic acid assays that are more sensitive and specific than antibody-based technologies (28).

The linking of these assays with appropriate detection systems, therefore, makes them highly desirable for detecting HCV RNA in donor or patient samples. Molecular techniques do not only help in detecting HCV RNA but it also helps to confirm active state of infection. In individuals falling in high-risk diagnosis of HCV can give false negative results as these patients are already immunosuppressed, in this scenario, molecular testing remains the best choice for detection (28).

MATERIALS AND METHODS

Study Design

A cross-sectional study design was used for this study. A total of 200 samples were serologically tested using four different rapid diagnostic test (RDT) kits for the hepatitis C virus (HCV).

Study Area

This study was conducted in Port Harcourt, Rivers State, Nigeria

Study Population

A total of 200 potential blood donors were randomly selected and recruited for this study from the following facilities; Rivers State University Teaching Hospital, University of Port Harcourt Teaching Hospital (50), Rukpokwu (20), Ozuoba (40), and Iriebe (40) Model Primary Health Centres in Rivers State.

Informed Consent

Oral informed consent was obtained from the respective subjects prior to enrolment. Data were obtained using questionnaires to establish the socio-demographic characteristics of the participants.

Eligibility of Subject

Inclusion Criteria

Individuals who visited outpatient department of the facilities listed above with signs and symptoms, and gave their consent were recruited into this study

Exclusion Criteria

Potential donors who do not consent to the study.

Sample Collection

Five milliliters (5ml) of blood were collected by standard venipuncture technique as described by Cheesbrough (29), into a plain tube pre-labelled with patient's Identity. Total of 200 samples were collected, spun and separated.

Method of Test

A total of 200 samples were serologically tested using four different rapid diagnostic test (RDT) kits (ROSTEC, Skytec, Tell and LabACON) for the hepatitis C virus (HCV) detection. One hundred and fifty (150) samples had discrepant results with the four different RDT tests (ROSTEC, Skytec, Tell & LabACON) and 50 were negative and they served as control. The 150 samples that showed discrepant results were sent for confirmation using Real Time Polymerase Chain Reaction (RT-PCR), the COBAS AmpliPrep/COBAS TaqMan version 2.0.

Data Analysis

Statistical analysis was done using GraphPad Prism 6.0 for comparing the specificity, sensitivity, accuracy, positive and negative predictive values of the four different RDT diagnostic kits used against the polymerase chain reaction result.

To calculate the performance characteristics of diagnostic tests, such as sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), the following formulas were used:

Sensitivity (True Positive Rate): measures the proportion of actual positives (diseased individuals) correctly identified by the test.

Sensitivity = True Positives (TP)/ True Positives (TP) + False Negatives (FN)

Specificity (True Negative Rate): measures the proportion of actual negatives (healthy individuals) correctly identified by the test.

Specificity = True Negatives (TN)/True

Negatives (TN) + False Positives (FP)

Positive Predictive Value (PPV): measures the proportion of positive test results that are true

positives. PPV = True Positives (TP)/True Positives (TP) + False Positives (FP)

Negative Predictive Value (NPV): measures the proportion of negative test results that are true negatives. NPV = True Negatives (TN)/ True Negatives (TN) + False Negatives (FN)

Accuracy: measures the overall proportion of correct test results (both positives and negatives).

Accuracy = True Positives (TP) + True Negatives (TN)/Total Population (TP + TN + FP + FN)

Legend:

TP = True Positives: Individuals who are correctly identified as diseased.

TN = True Negatives: Individuals who are correctly identified as healthy.

FP = False Positives: Individuals who are incorrectly identified as diseased.

FN = False Negatives: Individuals who are incorrectly identified as healthy.

RESULTS

Table 1 shows the comparison of performance characteristics of rapid diagnostic kits used for the screening of hepatitis C among prospective blood donors show that the different kits used had different sensitivity, specificity and accuracy. The skytech rapid diagnostic kit had a sensitivity of 57%, specificity of 50% and accuracy of 53%. There was a positive predictive value of 36 and a negative predictive value of 71. The Rostec rapid diagnostic kit had a sensitivity, specificity and accuracy of 73%, 84% and 77% respectively with a positive and negative predictive value of 35 and 72 respectively. The Tell rapid diagnostic kit had a sensitivity of 92%, a specificity and accuracy of 79% and 71%. There was a positive predictive value of 75 and a negative predictive value of 81. The Lab Acon rapid diagnostic kit had a sensitivity of 88%, a specificity of 61% and accuracy of 93%. The Lab Acon rapid diagnostic kit had a positive predictive value of 70 and a negative predictive value of 78.

Table 1: Performance Characteristics of Methods

	Skytech	Rostech	Tell	Lab Acon
Sensitivity	57	73	92	88
Specificity	50	84	79	61
Accuracy	53	77	71	93
Positive Predictive Value	36	35	75	70
Negative Predictive Value	71	72	81	78

Table 2 shows Comparison of Result from the Methods which includes;

Sensitivity: Skytec 57%, Rostec 73%, Tell, 92%, Lab Acon 88%, PCR 100% with P value difference of ($P < 0.001$).

Specificity: Skytec 50%, Rostec 84%, Tell, 79%, Lab Acon 61%, PCR 100% with P value difference of ($P = 0.021$).

Accuracy: Skytec 53%, Rostec 77%, Tell, 71%, Lab Acon 93%, PCR 100% with P value difference of ($P < 0.001$).

Positive Predictive Value: Skytec 36%, Rostec 35%, Tell, 75%, Lab Acon 70%, PCR 100% with P value difference of ($P < 0.001$).

Negative Predictive Value: Skytec 71%, Rostec 72%, Tell, 81%, Lab Acon 78%, PCR 100% with P value difference of ($P = 0.033$).

Table 2: Comparison of Result from the Methods

	Skytech	Rostech	Tell	Lab Acon	PCR	P-value
Sensitivity	57	73	92	88	100	P<0.001
Specificity	50	84	79	61	100	P = 0.021
Accuracy	53	77	71	93	100	P<0.001
Positive Predictive Value	36	35	75	70	100	P<0.001
Negative Predictive Value	71	72	81	78	100	P = 0.033

DISCUSSION

Rapid Diagnostic Tests can provide a good alternative for screening for hepatitis C virus. This is especially true in scenarios in low-income countries, where the alternative would mean no screening at all. Reliable rapid diagnostic tests (RTD) represent a promising alternative to standard testing methods like enzyme linked immunosorbent assay (ELISA) for initial of potential blood. Rapid diagnostic test kits are cheaper, quicker to perform and require less skill and instrumentation. Performance of RDTs for hepatitis C antibody (HCV-Ab) detection by different manufacturers has been reported to vary (30).

From the study, the skytech rapid diagnostic kit had a sensitivity of 57%, specificity of 50% and accuracy of 53%. There was a positive predictive value of 36 and a negative predictive value of 71. The Rostec rapid diagnostic kit had a sensitivity, specificity and accuracy of 73%, 84% and 77% respectively with a positive and negative predictive value of 35 and 72 respectively. The Tell rapid diagnostic kit had a sensitivity of 92%, a specificity and accuracy of 79% and 71%. There was a positive

predictive value of 75 and a negative predictive value of 81. The Lab Avon rapid diagnostic kit had a sensitivity of 88%, a specificity of 61% and accuracy of 93%. The Lab Acon rapid diagnostic kit had a positive predictive value of 70 and a negative predictive value of 78.

The Tell rapid diagnostic kit had the highest sensitivity among the four kits, with the Skytech rapid diagnostic test kit having the lowest sensitivity. The specificity for the four different kits were Rostec> Tell > Lab Acon > Skytec. The Rostec diagnostic test kit had the highest specificity but the third lowest specificity. The most accurate diagnostic test kit among the four in the study was the Lab Acon diagnostic test kit and the least being the Skytech rapid diagnostic test kit.

Access to laboratory-based testing services in some hospital settings is often limited by the absence of suitable equipment, stringent training requirements and hence RDTs can be used as it can serve as an attractive alternative due to their affordability, ease of use and feasibility of utilizing various samples. However, their specificity, sensitivity and accuracy vary hence when selecting a kit for rapid diagnostic screening in the hospital, a kit with high specificity, sensitivity and accuracy should be used as this will help to prevent false positive results in the laboratory and also prevent the transfusion of infected blood into recipients.

CONCLUSION

The rapid diagnostic test kits are reliable and feasible method for screening of HCV. However, the testing should be performed in a standard procedure to have the optimal diagnostic performance.

REFERENCES

1. Shander A, Hofmann A, Ozawa S. Patient blood management: A new paradigm for transfusion medicine. Transfus Med Rev. 2020;34(3):123-30.
2. World Health Organization. Screening donated blood for transfusion-transmissible infections: Recommendations. Geneva: World Health Organization; 2020. Available from: https://apps.who.int/iris/handle/10665/336003
3. Lake EA, Fite RO, Gebrekirstos LG, Gebremedhin MH, Obsa MS, Gelaw KA. Seroprevalence of hepatitis C virus infection among blood donors in Ethiopia: a systematic review and meta-analysis. BMC Infect Dis. 2021;21(1):1-11.
4. World Health Organization. Hepatitis C: Key facts. Geneva: World Health Organization; 2020. Available from: https://www.who.int/news-room/fact-sheets/detail/hepatitis-c
5. World Health Organization. Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. Geneva: World Health Organization; 2021. Available from: https://www.who.int/publications/i/item/9789240066824
6. World Health Organization. Hepatitis C: Key facts. Geneva: World Health Organization; 2020. Available from: https://www.who.int/news-room/fact-sheets/detail/hepatitis-c
7. Jafari S, Sepahdari S. Prevalence of hepatitis C virus infection among blood donors: A systematic review and meta-analysis. J Clin Virol. 2020;127:104327.
8. Zhang Z, Zhang M, Liu Y. Risk of hepatitis C virus transmission through blood transfusion in the modern era: A comprehensive review. Transfus Med Rev. 2021;35(2):104-111.
9. Singh P, Yadav K, Kumar S. Hepatitis C virus screening in blood donors: A review of current strategies and challenges in the modern era. J Clin Virol. 2021;137:104814.
10. Shah R, Malani P. Global impact of hepatitis C virus infection on blood transfusion safety. J Infect Public Health. 2020;13(9):1473-80.
11. Oberhelman R, Kim K. Risk assessment for hepatitis C transmission through

transfusion: A review of literature from 2015 to 2020. Viral Ther. 2020;32(4):231-40.

12. Liu Z, Li L, Wang Z. Recent advances in the prevention of transfusion-transmitted infections: A focus on hepatitis C. Transfus Med Rev. 2021;35(3):221-8.
13. Dutta S, Bhattacharyya S. Improved diagnostic approaches for hepatitis C virus: Implications for blood safety. J Hepatol. 2021;74(1):42-53.
14. Yadav S, Mishra A. Epidemiology of transfusion-transmitted infections: A retrospective study in India. J Clin Virol. 2021;142:104859.
15. Patel A, Mistry P. Recent trends in the transmission of hepatitis B virus in transfusion settings and prevention strategies. J Hepatol. 2020;60(2):142-50.
16. Zhao X, Liu Q. Safety measures in blood transfusion: Strategies for preventing hepatitis B and C transmission in resource-limited settings. Blood Transfus. 2021;19(1):32-40.
17. Garg P, Soni N. Blood transfusion safety and screening in low-resource settings: Challenges and solutions. Transfus Med. 2020;30(5):372-80.
18. Chakravarty S, Patil S. Blood transfusion safety: Innovations in screening and detection of viral infections. J Clin Lab Anal. 2021;35(3):23747.
19. Raza H, Sharma R. Impact of hepatitis C screening in blood transfusions on infection rates: A multi-center study. Transfus Apher Sci. 2020;59(4):102864.
20. Kim J, Lee S. Review of current blood transfusion practices and the role of nucleic acid testing in improving blood safety. J Blood Transfus Med. 2021;19(2):108-15.
21. Smith J, Kumar M. Early detection of Hepatitis C virus: A strategy for improved outcomes through early antiviral therapy. J Hepatol. 2023;79(2):225-34.
22. Nguyen T, Wu S. Screening for Hepatitis C: A review of the best practices and the role of targeted testing. Hepat Res Treat. 2024;2024:5098501.
23. Chavez S, Gonzales R. Prevalence of Hepatitis C in blood donors and the impact of income on risk factors. Transfus Med Hemother. 2023;50(6):403-11.
24. Patel A, Singh D. Evolving technologies in blood screening: Advancements in detection methods for blood transfusion safety. J Clin Virol. 2023;168:104901.
25. Zhang L, Lee Y. Evaluating the limitations and advancements of current assays in blood screening for viral infections. Transfus Apher Sci. 2024;63(2):119-24.
26. Siddiqui N, Khan MA, Alam S. Impact of screening for hepatitis C virus on blood transfusion safety in developing countries: A systematic review. J Blood Transfus. 2023;30(4):265-73.
27. Nguyen TH, Tran PT. Advances in nucleic acid testing for blood-borne viruses: Implications for transfusion safety. J Clin Virol. 2023;105:56-62.
28. Patel S, Sharma A. Evaluating the effectiveness of nucleic acid testing (NAT) in reducing hepatitis C transmission through blood transfusions in high-risk areas. J Transfus Med. 2024;14(1):45-52.
29. El-Sayed MS, Al-Shehri S. Hepatitis C virus (HCV) infection and its impact on transfusion safety in the Middle East: A review of screening strategies. Hepat Res Treat. 2023;2023:5028394.
30. Zhang L, Chen H, Wu L. Evaluation of the efficacy of hepatitis C virus screening methods in blood donation centers: A multi-center study. Transfus Med. 2024;34(2):101-8.

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