COMPARATIVE ASSESSMENT OF THE SENSITIVITY AND ACCURACY OF RAPID TEST KITS FOR EARLY INFANT DIAGNOSIS OF HIV

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ABSTRACT

The importance of early infant diagnosis (EID) of HIV in resource-limited countries cannot be overemphasized and it is critical to improving neonatal survival and reducing the risk of neonatal death and future HIV transmission. In this study, the sensitivity and accuracy of the Rapid test kits (RTK) Determine and Unigold on infants aged 6 months to less than 18 months was determined using DNA Polymerase Chain Reaction (DNA PCR) as the gold standard. A total of 236 samples were tested with the RTKs and DNA PCR. Out of 236 samples, 204 (86%) had matching results, with the DNA PCR while 32 (14%) did not match with the DNA PCR result. The non-corresponding results were observed to have occurred at age range of 6 months to 12 months, however, children aged 13 months to 17 months all had corresponding results between rapid test kits and DNA PCR. The 14% non-corresponding results were all false positives without any false negatives indicating that our RTKs were 100% sensitive to the detection of HIV infection among infants when compared to DNA-PCR. The specificity of our RTKs was also found to be 82.3%. This study shows that the RTKs, Determine and Unigold fared well $p < 0.05$ against the DNA PCR in our community and therefore can be used in resource-limited areas as screening tests for infants before a confirmatory test can be conducted. This will greatly reduce the cost of EID of HIV in infants and make it easily accessible in poor communities

BACKGROUND

Pediatric Human Immunodeficiency Virus (HIV) infection remains a significant public health problem in resource-limited countries, particularly in sub-Saharan Africa with over 70% of the global burden of infection (Kharsany and Karim, 2016). Therefore the importance of early infant diagnosis (EID) of HIV cannot be over emphasized and it is critical to improving neonatal survival and reducing the risk of neonatal death and future HIV transmission. Majority of these deaths occur in resource-limited areas due to inability to diagnose the infection/disease due to lack of equipment necessary to make diagnosis (NTCPHA, 2009)

MATERIALS AND METHODS

Study Area and Population

This prospective study was carried out among infants who were on follow up at Prevention of Mother to Child Transmission (PMTCT) clinic Nnamdi Azikiwe University Teaching Hospital (NAUTH), Nnewi, Anambra State, South East-Nigeria..

Determination of accuracy and sensitivity of rapid test kits

In this study, the sensitivity and accuracy of the Rapid test kits (RTK) Determine and Unigold on infants aged 6 months to less than 18 months is determined using DNA Polymerase Chain Reaction (DNA PCR) as the gold standard. A total of 236 samples were tested with the RTKs and DNA PCR

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Table 1: Comparison of RTKs against DNA PCR Among study subjects

	PCR (%)	Determine (%)	Unigold (%)
Positive	56 (23.7)	86 (36.4)	86 (36.4)
Negative	180 (76.3)	150 (63.6)	150 (63.6)
Total	236	236	236

Table 2: Distribution of corresponding and discordant results among different age groups in the use of DNA PCR and RTK

AGE GROUP				
	6-8 MONTHS	9-11 MONTHS	12-14 MONTHS	15-17 MONTHS
CORRESPONDING (%)	63 (90)	105 (81.4)	23 (95.8)	13 (100)
DISCORDANT (%)	7 (10)	24 (18.6)	1 (4.2)	0 (0)
TOTAL	70	129	24	13

RESULTS

Out of 236 samples, 204 (86%) had matching results with the DNA PCR while 32 (14%) did not match. The non-corresponding results were observed to have occurred at age range of 6 months to 12 months, however, children aged 13 months to 17 months all had corresponding results between rapid test kits and DNA PCR. The 14% non-corresponding results were false positives without any false negatives indicating that RTKs were 100% sensitive to the detection of HIV infection among infants when compared to DNA-PCR. The specificity of the RTKs was also found to be 82.3%.

CONCLUSION

This study shows that the RTKs, Determine and Unigold fared well $p < 0.05$ against the DNA PCR and therefore can be used in resource limited areas as screening tests for infants before a confirmatory test can be conducted. This will greatly reduce the cost of EID of HIV in infants and make it easily accessible in poor communities.