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A Comparative Study of Rapid Screening Tests with Elisa for the Diagnosis of HBV & HCV Infections among blood Donors Attending Tertiary Care Hospital.

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ABSTRACT

INTRODUCTION: Globally, the spread of HBV and HCV represent a serious threat to public health. In settings with limited resources, testing laboratories face a significant problem when attempting to identify infection signs for these agents. Although blood transfusions save millions of lives each year, there is a likelihood that they could be transmitting the viral infections like HBV and HCV.The purpose of the current study was to evaluate the relative sensitivity and specificity of rapid ICT to ELISA for the detection of HBV and HCV among blood donors.**MATERIALS AND METHODS**: A total of 184 serum samples were included in the study. One step rapid test for detection of HBSag and HCV was performed by using HEPACARD and HCV Tridot for detection of HBsAg and Anti-HCV antibodies.ELISA test was done by using Hepalisa and HCV Microlisa for detection of HBsAg and Anti-HCV antibodies.**RESULTS**: Out of 184 blood samples, 181samples were negative and 3 samples were positive by Rapid tests Whereas, 179 samples were negative and 5 samples were positive by ELISA. Rapid immunochromatography tests for HCV revealed that, out of 184 samples, 181 were negative and 3 were positive. This result was consistent with the findings of ELISA. **CONCLUSION**: The results bear a remarkable similarity to other previous studies carried out in India and other nations. It would be wise to use an ELISA or other specialized techniques to corroborate the findings of these point-of-care tests whenever possible.

I. INTRODUCTION

Blood transfusion service is a vital part of modern health care system which is an essential lifesaving-treatment but there is a risk of 1% chance of transmission of transfusion associated infections with every unit of blood.[1,2].Bloodborne viral infections are more prominent in blood transfusion.Some-times blood donors are not presenting with any signs and symptoms in spite of carrying an infectious agent[3]. Transfusion-transmitted infections (TTIs) remain a major health problem in most of the developing countries due to scarce resourcefacilities and staff members shortage[4].Transfusionof infected blood to the patient inneed is a crime[5].It is mandatory to screen the blood donors before transfusion for viral markers such as Hepatitis B (HBV) and C virus (HCV)to prevent the transmission of infection[6].Different methods are used to diagnose Hepatitis b &c including enzyme-linked immunosorbent assay (ELISA), enzyme immunoassays (EIA), polymerase chain reaction (PCR), and Rapid immunochromatographic tests (RICT) [7].

ELISA is recommended screening technique for blood in blood banksbut due to certain limitations of ELISA tests like unavailability in many blood banks, high cost, time taking and requirement of highly skilled personnel for interpretation of test most of the blood banks prefer to use rapid tests which are easy to perform and are user -friendly kits [8][9].

The aim of the current study was to compare the relative sensitivity and specificity of Rapid ICT to ELISA for the detection of HBV and HCV.

II. MATERIALS AND METHODS

This cross-sectional study was carried out on blood donors attending blood bank at Viswa bharathi Medical College and general hospital, Kurnool, Andhra Pradesh, India.EthicalCommittee approval and donor consent was taken. Total 184 samples were collected randomly from the donors and tested for Hepatitis B, Hepatitis C byRapid immunochromatographic test and ELISA.

Blood was collected in a 2ml vacutainer

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aseptically from blood bags and transported to the microbiology lab in an ice pack container to perform Rapid Immunochromatographic test and ELISA.

RapidImmunochromatographic tests were done by using HEPACARD and HCV tridotfor detection of HBsAg and Anti-HCV antibodies.

ELISA testwas done by using Hepalisa and HCV Microlisafor Detection of HBsAg and Anti-HCV antibodies respectively.

HEPACARD(J.Mitra.Pvt. Ltd)

HEPACARD is a rapidand qualitative test for the detection of Hepatitis B Surface Antigen (HBsAg) in Human Serum or Plasma.

HEPACARD is a one -step immunoassay based on the antigen capture, or "sandwich"principle. It uses monoclonal antibodies conjugated to colloidal gold and immobilized polyclonal antibodies on a nitrocellulose strip in a thin line. The test sample is introduced to and flows laterally through an absorbent pad where it mixes with the signal reagent[10]. If the sample contains HBsAg, it binds to the colloidal gold antibody conjugate forming an antigen antibody colloidal gold complex. Through thecapillary action complex migrates and meets the line of immobilized antibody (Test line) and forming an antibody-antigen-antibody colloidal gold complex, this forms a pink band indicating the sample is reactive for HBsAg[11].

Interpretation: - Results are noted andinterpreted as per manufactures guidelines. Appearance of pink coloured line in both test region "T" and control region "C" indicates that the sample is REACTIVE for HBsAg[10].

HEPALISA (J.Mitra.Pvt. Ltd) Microwell ELISA Test for the Detection of Hepatitis B Surface Antigen (HBsAg) in Human Serum/ Plasma.

Principle:HEPALISA is an enzyme-linked immunosorbent assaybased on the "Direct Sandwich" idea.Microwells are coated with Monoclonal antibodies with strong reactivity for HBsAg.The samples are added in the wells, followed by standard procedure.The amount of HBsAg present in the sample directly relates to the intensity of the blue colour developed. For inhibition of the enzyme-substrate reaction, stop solution is added and yellow colour developswhich is finally read at 450 nm spectrophotometrically. As per the manufacturer's guidelines test procedure & results were interpreted. Sample were interpreted as reactive for HBsAg as HBsAg positive or non-reactive for HBsAg as HBsAg negative[10].

HCV TRI-DOT

HCV TRI-DOT is a rapid, qualitative in vitro diagnostic test for the detection of antibodies to Hepatitis C Virus in human serum or plasma.

Principle: HCV TRI-DOT designed using modified HCV antigens representing the immune dominant regions of HCV antigen. These antigens are immobilized on a porous immune filtration membrane.

Interpretation: - Results are noted and interpreted as per manufactures guidelines. If test dots T1& T2, either both dark and light in colour (pink), it indicates that the sample isreactive for antibody to HCV. If only control dot appear it indicates that the sample is non-reactive for antibody to HCV[10].

HCV Micro ELISA test

HCV Microlisa is an enzyme linked immunosorbent assay for the detection of Anti HCV antibodies in human serum or plasma.HCV Microlisa utilizes a combined antigen sequence of both HCV structural and non-structural antigen i.e. CORE, E1, E2, NS3, NS4 and NS5.The results were read on Microplate spectrophotometer at 450 nm.

Cut off value was calculated as per the manufacturer's guidelines and the results were interpreted. According to their absorbance values, samples were interpreted as either reactive for HCV antibodyas HCV positiveor non-reactive for HCV antibody as HCV negative[10].

III. RESULTS

In our study, total of 184 blood samples were collected from the donors attending blood bank at Viswabharathi Medical College and general hospital, Kurnool, Andhra Pradesh, India. 184 samples were tested for HBsAg and HCV by Rapid immunochromatographic test and ELISA method. Out of 184 samples 3 samples found to be reactive for HBsAg and 3 samples found to be reactive for HCV by Rapid tests. After that the samples again subjected to the ELISAin which 5 samples found to be reactive for HbsAg and 3 samples found to be reactive for HCV.Total prevalence of hepatitis B and hepatitis C among blood donors in our study is2.7% and 1.6%

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Results in Rapid immuno chromatography and ELISA for Hepatitis B

	Positive	Negative	Total
Rapid immunochromatography	3(1.6%)	181(98.4%)	184
ELISA	5(2.7%)	179(97.3%)	184

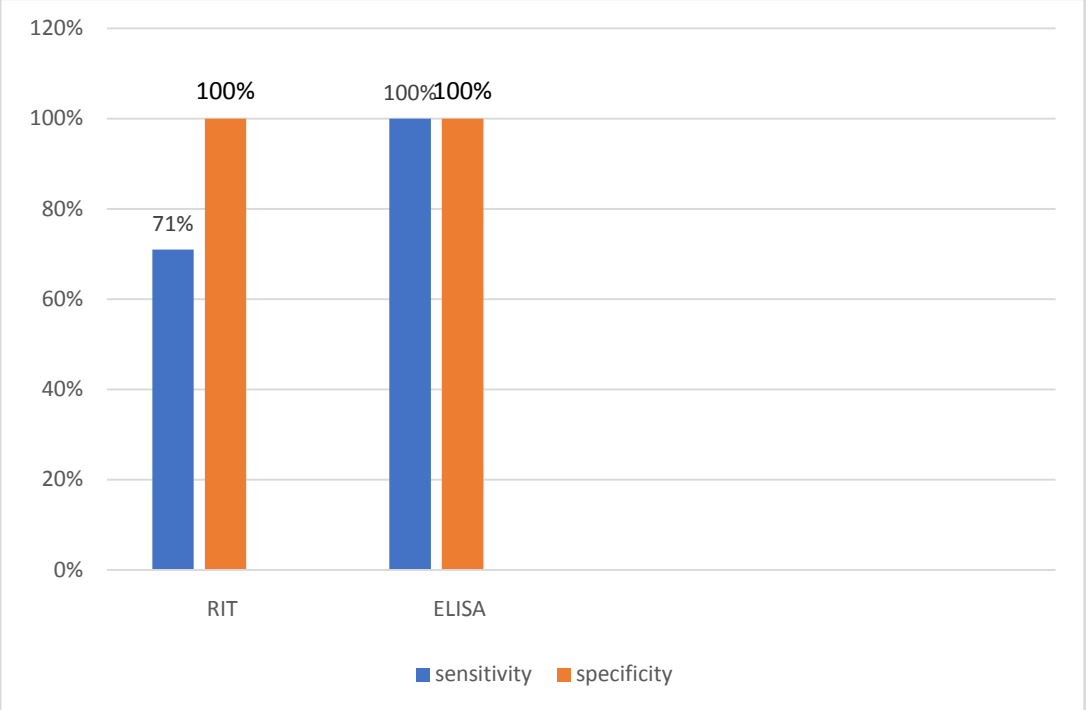
Out of 184 samples 181samples were negative and 3 samples were positive by Rapid immunochromatography whereas,179 samples were negative and 5 samples were positive by ELISA.

Results in Rapid immuno chromatography and ELISA for Hepatitis C

	Positive	Negative	Total
Rapid immunochromatography	3(1.6%)	181(98.4%)	184
ELISA	3(1.6%)	181(98.4%)	184

Rapid immunochromatography tests for HCV revealed that, out of 184 samples, 181 were negative and 3 were positive. This result was consistent with the findings of ELISA.

Sensitivity,Specificity0f Rapid immuno chromatography and ELISA for HbsAg



While the sensitivity and specificity of ELISA for HbsAg were 100%, the sensitivity and specificity of rapid immunochromatography were 71% and 100%, respectively.

Sensitivity, Specificity 0f Rapid immuno chromatography and ELISA for HCV

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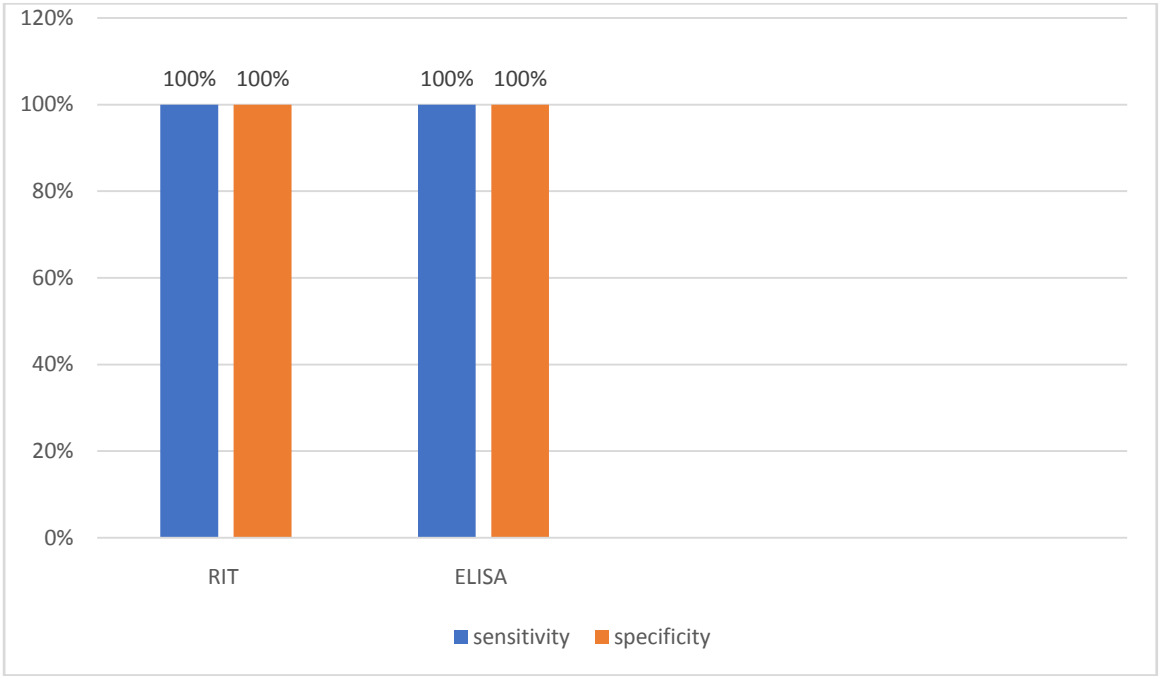

Sensitivity and specificity of both Rapid immunochromatography and ELISA for HCV is 100%

IV. DISCUSSION

Blood transfusion is a major life-saving measure but it is an important mode to transmit transfusion infections to the recipient[12].Among transfusion-transmitted infections, Hepatitis B and C are the major health problems associated with serious complications[13,14].

From a human and financial perspective, an unsafe blood transfusion is quite expensive. Transfusions of infectious blood can cause significant morbidity and mortality, which affect not only the recipients but also their families, communities,and larger society.

Failure to prevent infection transmission has an economic cost that includes increased medical care needs, a higher dependency level, the loss of a productive labor force, and a huge strain on the nation's already overburdenedsocial and health care systems[15].

It is required to test every blood unit for HIV, HCV, HBsAg, Syphilis, and malaria, asper the criteria of the National AIDS Control Organization (NACO) of India[15].

Detection of HBsAg and HCV infections is mainly based on immunological assays, among them ELISA and rapid tests are the most common[16,17]. An important issue encountered during diagnosis is the discordance between the results of two assays[18].

Our study objective was tocompare the sensitivity and specificity of Rapid immunochromatography&ELISA, for hepatitis B and C infections among blood donors attending blood bank in a tertiary care hospital.Inourstudytotalof184sampleswerecollected fromblooddonors and subjected to different diagnostic tests like Rapid immunochromatography and ELISA to know Hepatitis B and C infection among Blood donors.

Out of 184 samples only 3 samples were positive and remaining 181 were negative for HBsAgby rapid immunochromatography tests whereas,5 samples were positive &remaining 179 were negative by ELISA.Our study shows high positivity in ELISA compared to Rapid Immunochromatography.

In our study the Rapid test showed 75% sensitivity and 100% specificity while ELISA showed 100 % sensitivity and specificity for both HBsAg and HCV.

prabhaet al studies showed sensitivity of immunochromatography test was 83.4%and specificity was 100% but the sensitivity and specificity of ELISA was 100% forHBsAg [19]

Erhabor O et al study showed sensitivity and specificity of immunochromatography was 76.9% and 100% respectively for HBsAgwhereas sensitivity and specificity of ELISA was 100%[20]

Neetu kukar et al studies reported ELISA was much more sensitive than Rapid immunochromatographyfor both HCV and HBsAg [11].

Sreedhar Babu et al studies reported that rapid tests were found to be 0% sensitive and99.9% specific for HCV[14].

Al-Matary et al studies reported sensitivity and specificity of rapid immunochromatographic test waslower compared to ELISA.Specificity results of the rapid test for HBV&HCVwere 91.2 and 99.7% respectively,while the sensitivity was 25–75% for HBV and 60–80% for HCV[21].

V. CONCLUSION:

Rapid diagnostic tests should be utilized in a tertiary care hospital during emergency hours, however ELISA test results are required for confirmation. Rapid tests were frequently used by hospitals and outside labs without internal confirmation. But due to erratic variables, there might be variations in their performance. Therefore, in order to prevent major health risks and the silent spread of serious HBV and HCV infections, it would be prudent to validate these point-of-care tests using ELISA or other specialized procedures.

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