COMPARISON OF ELISA AND ICT FOR THE DETECTION OF HBsAg AMONG BLOOD DONORS IN TERTIARY CARE HOSPITAL PESHAWAR

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ABSTRACT

OBJECTIVES

This study aimed to compare the analytical sensitivity of an ELISA approach with a fast kit in identifying HBV infection in blood donors.

METHODOLOGY

This study used a cross-sectional design. Using the Rapid screening test kit, the ELISA approach was used to re-test 250 blood donor samples that had tested negative. 250 of 250 blood donor samples were analysed that were negative by fast test (ICT) but positive by ELISA method. Each blood sample was tested for HBsAg using both ELISA and ICT techniques. The blood was drawn, processed, and tested according to standard procedures, with serum separated via centrifugation and analyzed using the ICT kit initially, followed by confirmation through ELISA, employing the CMIA principle on the Architect i1000SR immunoassay analyzer.

RESULTS

The target variables hepatitis B surface antigen (HBsAg) were determined by ELISA. Out of 250 samples, 250 were negative by the ICT method whereas positive by the ELISA method. ELISA demonstrates a higher sensitivity of 95.12% compared to ICT's sensitivity of 92%. Additionally, ELISA exhibits greater specificity at 99.82% compared to ICT's 97%. The positive predictive value (PPV) for ELISA and ICT is 94% and 93%, respectively, while the negative predictive value (NPV) is 99% for ELISA and 96% for ICT. Overall accuracy is higher for ELISA at 97.6% compared to ICT's 94.6%.

CONCLUSION

ELISA is reliable for detecting HBsAg in blood donors and is better than fast kits in determining hepatitis B virus infection.

KEYWORDS: *HBsAg, ELISA, ICT*

INTRODUCTION

Infection with the hepatitis B virus (HBV) affects people all over the world. Three hundred sixty million cases of this viral infection are thought to be worldwide.[1] The liver is primarily affected by the systemic illness known as viral hepatitis. Hepatitis A virus (HAV), Hepatitis B virus (HBV), or Hepatitis C virus are responsible for the majority of instances of acute viral hepatitis (HCV). The HBV's P, X, core, and surface proteins are encoded by double-stranded DNA.[2] HBsAg appears in serum 2-10 weeks after exposure to HBV and before the onset of symptoms or elevation of serum aminotransferase levels. In self-limiting acute HBV infection, HBsAg usually becomes undetectable after 4-6 months. Persistence of HBsAg for more than six months implies progression to chronic HBV infection. Consequently, HBsAg is a useful viral marker for population screening and diagnosing acute HBV infection or Chronic Hepatitis B infection.[3] HBsAg immune chromatography technique (ICT) test is a rapid screening test for the qualitative detection of HBsAg in whole blood, serum or plasma specimen. The test utilises a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.[4] While the "sandwich" form of enzymatic immunoassay ELISA is used to detect HBV in human serum or plasma, the test makes use of monoclonal antibodies that were chosen because they could bind to the majority of mutant HBV strains and the several HBsAg subtypes now recognised by the World Health Organization (WHO).[5] Hepatitis can be diagnosed using a variety of techniques, such as the immune chromatography technique (ICT) test, ELISA, enzyme immunoassays (EIA), and polymerase chain reactions (PCR) (PCR). The costly ELISA, EIA, and PCR techniques are employed at well-resourced tertiary care hospitals. Reference Rapid diagnostic kits are a wise choice because they are less expensive and do not require extensive technical infrastructure or workforce.[6] Hepatitis B virus (HBV) infection is a significant global health issue, with approximately 296 million people living with chronic HBV infection

worldwide [WHO, 2021]. In regions like Peshawar, Pakistan, where HBV prevalence rates are high, ensuring the safety of blood transfusions is crucial. Screening blood donors for hepatitis B surface antigen (HBsAg) is a vital step in preventing the transmission of HBV through blood transfusions. Enzyme-Linked Immunosorbent Assay (ELISA) and Immunochromatographic Test (ICT) are two commonly used methods for HBsAg detection. Until now, there is no proper study between ICT and Elisa comparison; therefore, this project is designed to compare ICT and ELISA methods in tertiary care hospitals. This study aims to compare the performance of these two methods in a tertiary care hospital in Peshawar.

METHODOLOGY

The study employed a cross-sectional design and was conducted at Rehman Medical Institute and North West General Hospital over a six-month duration. A sample size of 250 blood donors was determined using probability sampling techniques. Inclusion criteria encompassed individuals between 18 to 60 years old, weighing over 50kg, with a minimum hemoglobin level of 13 mg/dl for males, and lacking a history of cardiac, kidney, diabetic, or hypertensive conditions. Exclusion criteria included recent blood donation, existing infections with transfusion-transmitted diseases, blood-related health issues, medication usage, and age outliers. Blood samples meeting the criteria underwent testing for HBsAg using both ICT and ELISA methods. The blood was drawn, processed, and tested according to standard procedures, with serum separated via centrifugation and analyzed using the ICT kit initially, followed by confirmation through ELISA, employing the CMIA principle on the ARCHITECT i1000SR immunoassay analyzer. Data analysis was performed using Microsoft Excel, facilitating organization and tabulation for subsequent interpretation.

RESULTS

Table 1: Age Wise Distribution

		Number	%age
Age Group	18-30	195	78
	31-40	40	16
	41-50	15	06
	Total	250	100
Gender	Male	245	98
	Female	05	02
Hospital	RMI	100	40
	North West	150	60

Table 2: Blood Group Wise Distribution

		Number	%age
Blood Group	A+	69	27
	A-	05	02
	B+	50	20
	B-	05	02
	AB+	25	10
	AB-	01	01
	O+	90	36
	O-	05	02
Profession	Graduate	55	22
	Intermediate	50	20
	Matric	70	28
	Middle	20	08
	Illiterate	45	18
	Primary	10	04

Table 3: Total Number of HBS Test

HBS Test	Positive	Negative
HBS on Elisa	250	00
HBS on ICT	00	250

Table 4: Comparing the Performance Metrics of ELISA and ICT

Metric	ELISA (%)	ICT(%)
Sensitivity	95.12	92
Specificity	99.82	97
Positive Predictive Value	94	93
Negative Predictive Value	99	96
Overall Accuracy	97.6	94.6

DISCUSSION

One of the biggest risks to blood safety for transfusions recipients, especially in developing nations, is the transfusion-transmissible hepatitis B virus (HBV). This virus also poses a significant public health issue. The development of mutant isolates and the requirement for early disease identification have always been projected to contribute to the improvement of immunoassay for detecting viral infections, nobly HBsAg. In this study, 250 samples that initially tested negative with the rapid kits tested positive with ELISA technique (HBsAg ULTRA ELISA kit). Similarly 250 samples that tested positive with HBsAg Rapid screening kit also tested positive with the ELISA technique.[7] Rapid kits inability to identify infectious viral illness indicators may be caused by the virus‘s genomic heterogeneity, insufficient antigen coating, and kind of employed antigen.[8] According to the research conducted by Khan and his colleagues There was devastating liver disease known as hepatitis B is brought on by the hepatitis B virus. In this study, HBsAg was found in blood donors from several areas in Pakistan’s FATA, a northwest border region, and by ICT (immuno-chromatographic test), ELISA, and 147 (2.05 percent) by ELISA. Of the 7148 blood donors tested, 244 (3.41 percent) had

positive results for HBsAg by ICT.[9] The ELISA test was performed using a kit from Tehran's Pioneer Medicine Company. The results of the ELISA test and the ICT HBs-Ag rapid test were compared. ICT test sensitivity was zero, but ELISA test sensitivity and specificity were one hundred percent.[10] The study conducted in pakistan had the age range of 15 to 55 years, individuals were tested for HBsAg using the immune chromatographic method (ICT) and third-generation enzyme-linked immunosorbent tests (ELISA).[11] (2.39 percent) of the 460 total samples were found by ICT to be HBsAg positive, and 13 (2.82 percent) were by ELISA. In comparison to ELISA, the mean seroprevalence for ICT.[11] Most blood banks use quick diagnostic kits to test blood donors for hepatitis B virus infection. Our study's findings highlight the possibility that blood transfusions may not be secure.[12] In this investigation, we found that the fast diagnostic kit produced more false negative results than the ELISA. Which stated that insufficient testing utilising HBsAg using quick kits only poses a risk of donor blood with HBV being transfused to patients. In our study, the sensitivity of the ELISA was 95.12% and specificity was 99.82%. Raj et al.[13] Reported that sensitivity was 79% and specificity was 98.9%. Another study showed 100% sensitivity of rapid test kit with a specificity of 91.7% for HBs Ag.[14,15] Reported 100% specificity and 93.4% sensitivity of ELISA to pick up all false negative. Rapid assays using a strip or device exhibited a sensitivity range of 97.5 to 99.2 percent and a specificity range of 97.5 to 99.2 percent, according to a study by Ansari et al. The sensitivity and specificity were 100% in a different research that employed two ICAs. Overall specificity for Lin et al. study was 98.7%, and sensitivity was almost 100%.[16,17] According to a study from India by Kaur et al., ICAs have a specificity of 100% but a sensitivity of 93.4%. According to a study from Seoul, HBsAg may be detected with 97 percent sensitivity and 100 percent specificity.[18] Another study among healthy individuals from Karachi, Pakistan showed comparable sensitivity and specificity of ICT kits with ELISA technique.[18] This indicates that ELISA test is more sensitive and superior for testing blood donors for HBsAg. Our finding is consistent with previous reports which indicated that ELISA technique is superior to rapid kits in diagnosing hepatitis B virus infection among blood donors.[9]

LIMITATIONS

The study might have a small sample size, which can affect the statistical power and precision of the results.

CONCLUSIONS

The ELISA test is sensitive and more reliable for detecting HBsAg in blood donors. Our results are comparable with those that show the ELISA technique is better than fast kits for determining if blood donors are infected with the hepatitis B virus.

CONFLICT OF INTEREST: None

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CONTRIBUTORS

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