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DETECTION OF HEPATITIS B VIRUS BY RAPID AND ELISA TEST METHODS AND THEIR COMPARISON & CLINICAL CORRELATION IN A TERTIARY CARE HOSPITAL.

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ABSTRACT

Background: Hepatitis B can be a serious liver disease that results from infection with the Hepatitis B virus. Acute Hepatitis B refers to a short-term infection that occurs within the first 6 months after someone is infected with the virus. It can cause chronic liver disease and puts people at high risk of death from cirrhosis of the liver and liver cancer. The main objective of this study was detection of Hepatitis B Virus by Rapid and ELISA test methods and their comparison & clinical correlation in a tertiary care hospital.

Methods: The present study was a cross sectional and comprised of all the clinical specimens of blood referred to microbiology laboratory from patient of all age groups that comes in Late Baliram Kashyap Memorial Govt. Medical College and hospital, Jagdalpur, Chhattisgarh. Duration of the study was from March 2019-May 2019. The study was conducted on 1250 clinical specimens. An informed written consent was obtained from all the patients who were enrolled.

Results: Maximum no. of patients was from 21-30 years of age. The female to male ratio was 1.53:1. A clinical sample was more commonly from female patients. It was observed that (1.04%) samples were positive by rapid test and (98.96%) were negative by this rapid test.

Conclusion: The rapid diagnostic test kit gives result in 20 minutes so that can be used in emergency situation. When there is need for testing of blood sample prior to apheresis procedure or when emergency blood issue needs to be done, rapid diagnostic test useful.

KEYWORDS : Hepatitis B, ELISA Test, Rapid Test, Clinical correlation.

INTRODUCTION:

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus which is a major global health problem. It can cause chronic liver disease and puts people at high risk of death from cirrhosis of the liver and liver cancer.[1] Hepatitis B virus is a member of Hepadna virus family. It is a DNA virus surrounded by an envelope which contains HBsAg surface antigen which is important for laboratory diagnosis and immunization. In addition to HBsAg, there are two other important antigens: Core antigen (HBcAg) and e antigen (HBeAg).HBsAg is an indicator of transmissibility. All persons who are HBsAg positive are potentially infectious.[2]

It is estimated that 240 million people are chronically infected with hepatitis B, and almost 686,000 people died yearly due to the complications caused by the infection.[3] HBV uses an encoded enzyme reverse transcriptase to replicate its viral genome. Reverse transcription is an error-prone process that generates a large number of nucleotide changes within the viral genome. This process results in new, closely-related viral species; as a result, at any given time in a particular host the viral population consists of a swarm of similar but discrete viruses.[4]

There are four known genes encoded by the genome called C, X, P and S. The core protein is encoded for by gene (HBsAG) and its start codon is preceded by an upstream in-frame AUG start codon from which the pre-core protein is produced. HBeAg is produced by proteolytic processing of the pre-core protein. The DNA polymerase is encoded by gene P gene S is the gene that codes for the surface (HBsAg). The HBsAg gene is one long open reading frame but contains three in frame start (ATU) codons that divide the gene into three sections; pre-S1, pre-S2 and S.[5]

Transmission of hepatitis B virus results from exposure to infectious blood or body fluids containing blood. Possible forms of transmission include (but are not limited to) unprotected sexual contact, blood transfusions, reused of contaminated needles and syringes, and vertical transmission from mother to child during childbirth. Without intervention, a mother who is positive for HBsAg confers a 20% risk of passing the infection to her offspring at the time of birth. The risk is as high as 90% if the mother is also positive for HBeAg. Hepatitis B virus can be transmitted between family members within households, possibly by contact of non-intact skin or mucous membrane with secretions or saliva containing hepatitis B virus. However, about 30% of reported Hepatitis B among adult cannot be associated with an identifiable risk factor Other risk factors for developing hepatitis B virus infection include working in a health care setting, transfusions and dialysis, acupuncture, tattooing, extended overseas travel and residence in a research institution[6].

METHODS:

The present study was a cross sectional, descriptive study and comprised of all the clinical specimens of blood referred to microbiology laboratory from patient of all age groups and both sexes that comes in Late Baliram Kashyap Memorial Govt. Medical College and hospital, Jagdalpur, Chhattisgarh. Duration of the study was from March 2019-May 2019.

The study was conducted on 1250 clinical specimens of blood referred to microbiology laboratory from patient of all age groups and both sexes that comes in Late Baliram Kashyap Memorial Govt. Medical College and hospital, Jagdalpur, Chhattisgarh.

The study population was comprised of patients comes in various out patients (OPD) and in patients departments (IPD) of the hospital including various surgical wards, Obstetrics and gynecology ward, Medicine ward, Pediatric ward, orthopedic ward, Eye ward, Burn ward, ICU, Emergency. The following data was collected Patients – Age, sex, brief history, diagnosis, address, education, occupation, socioeconomic status, and personnel habits. Materials required for the study are: Disposable gloves, Disposable Syringe and Needle, Evacuated collection tube, 70% ethanol, Tourniquet, Cotton, Eppendrorf tube, Centrifuge, Gloves, Clock or Timer, Needle Cutter, Waste Disposal. An informed written consent was obtained from all the patients who were enrolled for the study.

Inclusion criteria:

All the clinical specimens of blood referred to microbiology laboratory from patient of all age groups and both sexes that comes in Late Baliram Kashyap Memorial Govt. Medical College and hospital, Jagdalpur, Chhattisgarh.

Exclusion criteria: No exclusion criteria.

RESULT:

Table 1: Age distribution of patients

Age groups (yrs.)	Male/Female		Total n (%)
	Male	Female	
0-10	28	22	50 (4)
11-20	69	135	204(16.32)
21-30	134	402	536 (42.88)
31-40	95	106	201 (16.08)
41-50	89	52	141 (11.28)

51-60	40	21	61 (4.88)
61-70	30	15	45 (3.6)
71-80	07	02	09 (0.72)
81-90	01	02	03 (0.24)
Total	**493**	**757**	**1250 (100)**

Maximum no. of patients was from 21-30 years of age. Age of the patients in males ranged from newborn to 80 years and females 3 yrs. to 90 yrs.

Table 2: Male and female distribution of 200 isolates

Male/Female	Male n (%)	Female n (%)
Total Number 1250 (%)	493 (39.44)	757 (60.56)

The female to male ratio was 1.53:1. A clinical sample was more commonly from female patients.

Table 3: OPD/IPD wise distribution of samples

OPD/IPD	OPD	IPD	Total
No. of samples (n) (%)	466 (37.28%)	784 (62.72%)	1250 (100%)

It was observed that highest number of sample was from in patients departments (IPD) d (62.72%).

Table 4: Rapid test wise distribution of samples

Rapid test	Positive	Negative	Total
No. of samples (n) (%)	13 (1.04%)	1237 (98.96%)	1250 (100%)

It was observed that (1.04%) samples were positive by rapid test and (98.96%) were negative by this rapid test.

Table 5: Elisa test wise distribution of samples

Elisa test	Positive	Negative	Total
No. of samples (n) (%)	13 (1.04%)	1237 (98.96%)	1250 (100%)

It was observed that (1.04%) samples were positive by Elisa test and (98.96%) were negative by this Elisa test.

Table 6: Elisa test wise distribution of positive samples

Elisa test Positive	Male	Female	Total
No. of samples (n) (%)	09 (69.23%)	04(30.77%)	13 (100%)

It was observed that samples positive by rapid test 09 were male and 04 were female.

Table 7: No. of positive samples by two different methods

No. of samples	Rapid test Positive	Elisa test Positive
Clinical samples n (1250)	+ve (13) -ve (1237)	+ve (13) -ve (1237)

It was observed that 13 samples were positive by rapid test and 12 were positive by this Elisa test.

DISCUSSION:

Rhim et al observed, under conditions of very acute liver injury, the replacement of virtually the entire hepatocyte population of the mouse by congenic outgrowth of mature hepatocytes. This required an average of at least 12 cycles of cell division. While hepatocytes may represent a fairly homogeneous population of quiescent cells at the time of infection.[7]

Hepatitis B is moderately endemic in part of Eastern and Southern Europe, the Middle East, Japan, and part of South America. Between 10–60% of the population have evidence of infection, and 2-7% is chronic carriers. Acute disease related to HBV is common in these areas because many infections occur in adolescents and adults; however, the high rates of chronic infection are maintained mostly by infections occurring in infants and children.[8]

According to Kerkar, the major findings of hepatitis B virus include: Diffuse liver cell injury with lobular disarray, Necrosis of random, isolated liver cells or small cluster of cell, Reactive changes of kuffer cells and sinusoidal living cells, an inflammatory infiltrate in the portal tract, Evidence of hepatitis regeneration during the recovery phase.[9]

According to Robinson HBsAg carriers should have regular serial serum AFP determinations and ultrasound examinations (at 6 months intervals for those above 40 years). These tests are recommended to be repeated regularly for all HBsAg carriers with cirrhosis.HBV causes 60-80% of the world's primary liver cancer, and primary liver cancer is one of the three most common causes of cancer deaths in males in East and South-east Asia, the Pacific Basin, and sub- Saharan Africa. Primary liver cancer is the eighth most common cancer in the world.[10]

Kaur *et al* reported 100% specificity and 93.4% sensitivity of ELISA to pick up all false negative and also has observed that ICAs has a specificity of 100% but the sensitivity was 93.4%.[11]

Khan et al. (2010) using two ICA based rapid assays for HBsAg detection found sensitivity to be 53% and 50%, respectively although the specificity was 100% and 95% respectively.[12]

CONCLUSION:

The rapid diagnostic test kit gives result in 20 minutes so that can be used in emergency situation when less time available to perform ELISA .When there is need for testing of blood sample prior to apheresis procedure or when emergency blood issue needs to be done, rapid diagnostic test useful and then subsequently can be tested by ELISA. But as sensitivity of rapid diagnostic test is varies, it cannot replace ELISA anyhow. ICT test must be used with caution and validation is required for these rapid assays by testing them in a given population to assess the effectiveness of these assays in detecting HBsAg in diagnostic laboratories. It should be carried out in poor settings or remote areas to assess prevalence of HBV infection and can help to prevent vertical transmission in some extent.

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Conflict of interest: Non declared

Ethical approval: The study was approved by the institutional ethics committee.

REFERENCES:

1) Barker LF, Shulman NR and Murray R. Transmission of serum hepatitis. JAMA.1970; 276 (10): 841-4.
2) Park K; Park's text book of prevention & social medicine, 15th edition. India MS Bannasidas Bhanot, 1997; 157-159.
3) Naghavi M, Wang H, Lozano R, Davis A, Liang X, et al. (2015) Global, regional, and national age-sex specific all-cause and cause specific mortality for 240 causes of death, 1990-2013: a systematic analysis for the global burden of disease study 2013. The Lancet 385: 117-171.
4) Torresi J, Earnest-Silveira L, Civitico G, Walters T, Lewin SR, Fyfe J, et al. Restoration of replication phenotype of lamivudine resistant hepatitis B virus mutants by compensatory changes in the "fingers" sub-domain of the viral polymerase selected as a consequence of mutations in the overlapping S gene. Virology 2002; 299:88-99. PMID: 12167344 oi: 10.1006/viro.2002.1448.
5) Galibert FJ, Mandert N, Fitoussi B, Toillais I, Charnay V. Nucleotide sequence of the hepatitis B virus genome (subtype ayw) cloned in E. coli. Nature.1979; 281: 646.
6) Glebe D, Urban T (2007) Viral and cellular determinants involved in hepadna viral entry. World J Gastroenterology 13(1): 22-38.
7) Rhim, J. A., E. P. Sandgren, J. L. Degen, R. D. Palmiter, and R. L. Brinster. Replacement of diseased mouse liver by hepatic cell regeneration. Science 1994; 263:1149–1152.
8) Toukan A. Strategy for control of hepatitis B virus infection in Middle East & North Africa. Vaccine. 1990; 8(suppl):S11-S12. [PubMed] [Google Scholar]
9) Kerkar N. Hepatitis B in children: complexities in management. Pediatric transplantation.2005; 9(5): 685-691.
10) Robinson WS. Hepatitis B virus and hepatitis D virus. In: Mandell GL, Bennett JE, Dolin R, eds. Principles and Practice of Infectious Diseases, 4th Ed. New York, Churchill Livingstone, 1995:1406-1439.
11) Kaur H, Dhanao J, Oberoi A. Evaluation of rapid kits for detection of HIV, HBsAg and HCV infections. Ind J Med Sci. 2000; 54: 432–4p.
12) Khan JK, Lone DS, HameedA, Munim MR, Bhatti M, Khattak AA et al. Evaluation of the performance of two rapid immunochromatographic tests for detection of HBsAg and anti HCV antibody using ELISA tested samples. Annals of King Edward Medical University 2010; 16(S1):84-7.