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COMPARISON OF ANTIBODY DETECTION BY RAPID DIAGNOSTIC KIT AND ELISA TEST FOR DIAGNOSIS OF HEPATITIS C VIRUS INFECTION

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ABSTRACT

Background: Hepatitis C virus (HCV) infection is a major cause of healthcare problem along with burden of health management care cost of international concern. Hepatitis C is a serious threat with long term complication. The present study is undertaken to compare rapid card test based on Immunochromatography principle with ELISA test for detection of anti HCV antibodies. In the absence of vaccine, primary prevention of Hepatitis C should be targeted to reduce transmission of virus. High risk people should be provided with education, counselling and screening. **Method:** A cross-sectional study was done at Dept. of Microbiology, M.G.M.M.C, Indore for one year comprising of 500 samples after getting Institutional Scientific Research and Ethics Committee approval. Rapid card and ELISA tests were performed in the samples received for detection of Anti-HCV ab. **Result:** Out of 500 blood samples tested on Rapid card 22 were positive while 478 were negative. Further testing on same 500 samples with ELISA test 22 were positive and 478 were negative. **Discussion:** Present study findings suggest that for screening of anti HCV antibody ELISA and Rapid card tests both can be used as diagnostic tool depending upon facilities available in the laboratory. **Conclusion:** Rapid card tests were found to be equally diagnostic as compared to ELISA test and hence can be recommended in screening of HCV.

KEYWORDS : HCV (Hepatitis C Virus), ELISA (Enzyme Linked Immunosorbent Assay), Anti-HCV ab(Anti-HCV antibodies

INTRODUCTION

hepatitis C virus belongs to Flaviviridae family (Refer figure no:1), genus Hepacivirus (from the Greek hepar, hepatos means liver). It is a spherical, enveloped virus with a diameter of around 55 nm. HCV genome is 9.6 kilo bases long. It is a positive sense single standard RNA virus. Its genome has one large open reading frame which accounts for over 95% of the sequence.

It encodes for a single large polyprotein, which is about 3010 amino acids long and it undergoes post transitional modifications to yield 10 viral proteins Flanking the ORF at both 5' and 3' ends are highly conserved untranslated regions (UTR), which mediate crucial steps in viral translation and replication[1-3].

HCV is transmitted by blood and blood products[4] .Hepatitis C virus can cause acute or chronic infection. Acute infections are usually asymptomatic or clinically mild. The infection is usually recognized only when it becomes chronic. Cirrhosis is a significant complication of chronic infection [5].

This is shown by several studies where the positivity rate for patients who transfused blood before 1995 was 16% and patients who received blood transfusion after 1995 was 6% [6].

In intravenous drug abuse antibody prevalence ranges from 5-93% whereas in hemodialysis patients it ranges from 4.3%-45.2% [7,8]. HCV has worldwide distribution, affecting persons of all ages, races, gender and regions of the world.

HCV accounts for more than 350,000 deaths annually, mortality in HCV infection is attributed to liver Cirrhosis and Hepatocellular carcinoma[9].

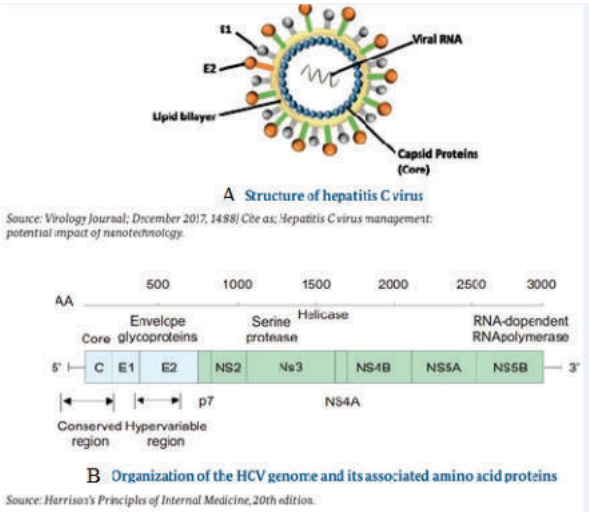

Figure:1 A Structure of HCV; B Organization of the HCV genome and associated AA proteins.

Blood transfusion and unsafe injection practices are believed to be major routes of transmission of HCV in India where about 20 million people are known to have been affected by HCV. It is estimated that in India, approximately 6-12 million people with Hepatitis C. Chronic HCV infection accounts for 12-32% of HCC and 12-20% of Cirrhosis [10].

AIM

To compare Rapid Immunochromatographic assay with Enzyme Linked Immunosorbent assay for detection of antibody against Hepatitis C virus.

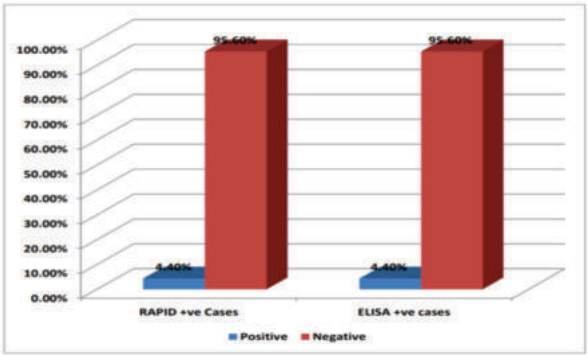

Figure: 2 showing comparison of RAPID and ELISA for detection of Anti-HCV antibodies.

METHOD

In this study, we tested 500 HCV blood samples over a period of one year from August 2021 to July 2022. Rapid card and ELISA tests were performed in the samples received for detection of Anti-HCV antibodies.

RESULTS

The serological assay was done for detection of Anti-HCV antibodies. Out of 500 samples tested for Anti-HCV antibodies 22(4.4%) were positive by RAPID and ELISA. (Refer figure no: 2)

In the present study, the risk factor for HCV transmission was observed as blood transfusion in 18 cases (81.81 %), haemodialysis in 1 cases (4.54%), unsafe injection in 2 cases (9.09%) and IV drug abuse in only one case (4.54%). (Refer figure no: 3)

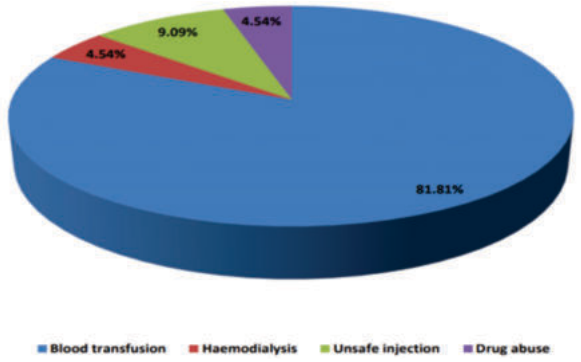

Figure: 3 showing distribution of risk factor for HCV.

DISCUSSION & CONCLUSION

Hepatitis C virus infection is a serious threat to health care system. It can cause varying clinical conditions ranging from acute infection to chronic Hepatitis and hepatocellular carcinoma. The prevalence of HCV varies in different parts of the country. The complex and uncertain nature of HCV infection and its chronicity emphasizes the difficulties in prevention and control of HCV [11].

The samples were subjected to serological test for detecting antibodies. In the present study, 500 samples were screened and 22(4.4%) were tested positive for Anti-HCV antibodies. This proportion is comparable with the seroprevalence of Anti-HCV 3.6% by Trickey A et al (2019) and 2.3% Manoj Kumar et al (2019) other studies reported previously[11,12,13,14,15].Present study findings suggest that for screening of anti HCV antibody ELISA test and Rapid card test both can be used as diagnostic tool depending upon facilities available in the laboratory.

Hepatitis C virus is transmitted primarily through the parenteral route and source of infection include transfusion of blood and its products, unsafe therapeutic interventions, drug abuse, needle stick injuries, hairdressing and tattooing[16].Most frequent risk factor for HCV transmission in this study was blood transfusion observed in 81.81% of cases followed by unsafe drug injections in 9.09%%, haemodialysis in 4.54%, drug abuse in 4.54%. Blood transfusion history was elicited in 81.8 1 % sero-positive cases. This finding correlates well with study by Amarapurkar et al which showed 38% and Abel Girma Ayele et al study with 21.5%. Blood transfusion was responsible for about 61% of cases with chronic HCV infection according to a study from Vellore by Seeff et al [17,18].

This could be attributed to the fact that blood transfusion allows a large quantum of infective virions into the susceptible patient [17] . Multiple blood transfusions and haemodialysis were also significant risk factors observed in this study, which could be explained by the fact that patients on haemodialysis are at an increased risk for acquiring HCV as a result of multiple blood transfusions and cross contamination from dialysis circuit. Stringent blood screening and Strict infection practices in dialysis unit are required for reduction of transmission[1] . The antibody protection is poor in patients on chronic haemodialysis and after renal transplantation due to immunosuppression. The ELISA alone may fail to detect the HCV infection in these cases. HCV RNA testing should be made mandatory for these patients [16] . Health care workers have an increased risk of acquiring Hepatitis infection. In many developing countries like India, an important risk factor for HCV is blood transfusion. In many places of India, supplies of sterile syringes may not be available or non-medical professionals often give injection outside the hospital. In this scenario, people may receive multiple contaminated injections over a period of time which increases the risk of HCV infection. Quatitative PCR are used to confirm the presence of Hepatitis C virus. RT-PCR used for quantitative measurement of viraemia for diagnosis in HCV infection[16]. The sensitivity and the specificity of RAIPD and ELISA in this study were 100%,99.8% and 100%,95% respectively. Though it was good enough as a diagnostic assay, all the ELISA positive cases should be confirmed by testing for HCV RNA, as the specificity of RT-PCR was absolute at high sensitivity (100%), which is not only suitable for clinical diagnosis and also recommended for the HCV screening in order to prevent the transmission of this disease [16].

In present study, results of Rapid card test are compared with ELISA test and observed that Rapid card test can also be used for screening of HCV antibody.

Advantages of Rapid kit over ELISA test:

- It is cheaper.
- It is less time consuming.
- It does not require expertise technical staff.
- Even single sample can be processed.
- No specific infrastructure is required.

Present study findings suggest that for screening of anti HCV antibody ELISA test and Rapid card test both can be used as diagnostic tool depending upon facilities available in the laboratory. Rapid card tests were found to be equally diagnostic as compared to ELISA test and hence they can be recommended in screening of HCV.

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