EFFICACY OF IMMUNOASSAY CHROMATOGRAPHY TEST FOR HEPATITIS-C ANTIBODIES DETECTION

Asia Batool, Misbahul Islam Khan, Khatoon Akhtar Bano
PMRC Research Centre, Fatima Jinnah Medical College, Lahore, Pakistan.

Objective: To asses the efficacy of commercially available tests device method for anti HCV detection. **Methods:** Total 2000 blood samples for detection of anti HCV were screened initially by immunochromatographic method. Those found positive on initial screening were re-tested by ELISA method at the Biochemistry Laboratory of the Pakistan Medical Research Council, Fatima Jinnah Medical College, Lahore. **Results**: Out of a total of 2,000 blood samples, 177 were found to be initially reactive/positive for anti-HCV with immunochromatographic method. When these reactive/positive samples were retested for confirmation with ELISA, 47 blood samples were found to have tested falsely positive for anti-HCV. Overall 2.35% of blood samples were found to be tested false positive for anti-HCV by immunochromatographic device method. **Conclusions:** Immunochromatographic device method test is rapid and simple, which can be used in setting with limited facility when rapid testing is required. However it should not be used as sole criteria for diagnosis but should serve the purpose of initial screening only. Further research is required to establish the reliability of such devices for their specificity and sensitivity.

Keywords: Immunochromatographic device test, Elisa testing method, anti-HCV, false positive

INTRODUCTION

The prevalence of HCV infection is much diversified according to geographical areas and ranges from 1% in the Northern regions of the world to more than 20% as we move south. Due to the presence of HCV associated liver diseases and the development of effective treatments, the diagnosis of HCV infection is a growing medical need. The diagnosis of infection has become a major health problem. The ideal test should be specific, reproducible, reliable and inexpensive.[1] The diagnosis may be used in conjunction with consideration of factors, as experience with a given test, availability, cost, service and trouble-shooting to help select assays appropriate to local needs.[2]

In recent years, considerable advances have been made in diagnostic testing for Hepatitis C Virus (HCV). The laboratory diagnosis of HCV infection is usually made on the basis of the detection of circulating antibodies. Serological tests for detecting antibodies to HCV are generally classified as screening test or confirmatory test. Screening test provide the presumptive identification of antibodies in specimens, whilst confirmatory test is used to confirm that specimens found reactive with a particular screening test contain antibodies specific to HCV.[2]

Several screening tests may be used in a testing to determine a final sero-status. Simple, instrument and electricity-free screening tests have been developed including agglutination, immunofiltration (flow through) and immunochromatographic (lateral flow) membrane tests. The immuno-chromatographic test is rapid and simple, and could be used along with rapid determination, in settings with limited facilities or when rapid results are required. While most of these tests can be performed in less than 10 minutes, other simple tests are less rapid and their performance requires 30 minutes to 2 hours.[3]

The second and third line tests are generally referred to as supplemental tests. The most widely used anti-HCV confirmatory tests are ELISAs as they are the more appropriate than screening test. A major concern in utilizing rapid screening tests is that they should have a high degree of sensitivity and a reasonable level of specificity so as to minimize false positive or false negative results.[4] The accuracy of screening test can be checked if additional supplemental or confirmatory test(s) of higher specificity are used to retest all those samples found reactive by the screening test device. Screening and supplemental tests, to be used in an HCV confirmatory strategy, must be selected carefully to ensure that common false reactivity between these assays does not occur.[2]

This study is as an attempt to evaluate false positive testing by screening test device and check efficacy of this method frequently used for screening purpose on large scale. These findings will be helpful for health policy makers, blood banks and national prevention and surveillance programme.

MATERIAL AND METHODS

From Nov 2007 to Oct 2008, total 2000 samples were tested for anti-HCV by simple immuno-chromatography rapid test device method in Biochemistry Laboratory of PMRC Research Centre, Fatima Jinnah Medical College, Lahore. The samples which were found to be positive during

screening by device were further re-tested for confirmation by ELISA method to check false positive results.

RESULTS

Out of total 2000 samples 177 (8.9%) were found to be initially reactive for anti-HCV when screened through immunochromatography technique, i.e., rapid test for detection of anti HCV. Later on these reactive samples (177) were retested by ELISA method for conformation. With ELISA method 47 samples were proved to be non-reactive for anti-HCV. The percentage of false positive results through immuno-chromatography test device was 2.35%.

DISCUSSION

Whenever, newer testing methodologies are employed the accuracy of such test, i.e., proportion of false positive and false negative must be noticed. Although the licensed screening tests are highly sensitive and specific, the likelihood of false positive result cannot be ignored.[5]

HCV infections rate has increased from 7.3% to 8.9% reported in our previous study conducted a year ago at the same centre.[6] In present study, the blood samples which were screened to be positive for anti HCV through rapid immunochromatography device test, retested with ELISA method to evaluate any false positive result. Retesting with ELISA method found that false positivity was 2.35% in samples screened through rapid immunochromatography device test. This showed a big difference reported in other studies where the overall false positive testing incidence by rapid immunochrpmatgraphy device was 0.15% for anti-HCV, HBV and HIV.[7]

The false positive results may be due to cross reactivity, recent vaccination, multiple transfusions and auto immune disease, alcohol use or any other viral infections.[8] A previous study showed that false negative results were associated with human immuno-deficient virus. Among HIV negative people sensitivity of rapid test for HCV antibodies was 99.2% whereas among HIV positive people sensitivity was 77.5%.[9] This leads to the fact that sensitivity of rapid test for HCV antibodies was decreased due to HIV virus. Therefore increase rate of false positive cases in the present study was may be due to unknown viral infections. In addition, in our country quality and storage of immunochromatic device may be questionable. The fall in sensitivity can also be explained by chance variation, inadequate representation of antigen on rapid device.[10]

CONCLUSION

The HCV detection through rapid immuno-chromatography device test should not be used as sole criteria for diagnosis of Hepatitis C. The study emphasizes that there is always need to establish quality control to find out the reliability of such devices for their specificity and sensitivity.

REFERENCES

1. Dal Molin G, Tiribelli C, Campello C. Rational use of laboratory tests in the diagnosis and management of Hepatitis C virus infection. Ann Hepatol 2003;2(2):76–83.
2. WHO. Hepatitis C assays: operational characteristics report. Blood safety and clinical technology. World Health Organization Geneva Report 2. 2001.
3. Wilber JC. Development and use of laboratory tests for Hepatitis C infections: a review. J Clin Immunoassay 1993;16:204–7.
4. Narayan S. Microbes and blood transfusion. Indian J Med Microbiol 2001;19(3):119–26.
5. Sayers MH, Beatty PG, Hansen JA. HLA antibodies as a cause of false-positive reaction. Sreening enzyme immunoassays for antibodies to human T-lymphotropic virus type-III. HLA antibodies as a cause of false-positive reaction. Transfusion 1986;26(1):113–5.
6. Batool A, Bano KA, Khan MI, Hussain R. Antenatal screening of women for hepatitis B and C in an out-patient department of Sir Ganga Ram Hospital Lahore. J Dow Uni Health Sci 2008;2(1):32–5.
7. Rahman M, Khan SA, Lodhi Y. Unconfirmed reactive screening tests and their impact on donors management. Pak J Med Sci 2008;24(4):517–9.
8. Wai CT, Tambyah PA. False-positive HIV-1 ELISA in patients with Hepatitis B. Amer J Med 2002;112(9):737.
9. Desbois D, Vaghefi P, Savary J, Dussaix E, Roque-Afonso AM. Sensitivity of a rapid immuno chromatographic test for hepatitis C antibodies detection. J Clin Virol 2008;41(2):129–33.
10. Raghuraman S, Subramaniam T, Abraham P, Sridharan G. Evaluation of a rapid assay for HCV antibody detection. Indian J Med Microbiol 1999;17(3):140–1.

Address for Correspondence:

Asia Batool, Research Officer, PMRC Research Centre, Fatima Jinnah Medical College, Lahore, Pakistan.
Email: asia_batoolpk25@yahoo.com