Evaluating immunochromatographic and ELISA methods in detection of anti-HCV antibodies among healthy blood donors: a pilot study

Blood transfusion services are a vital part of modern health care system. With every unit of blood there is 1% chance of transfusion associated problems including transfusion transmitted infectious disease acquisition. Transfusing infected blood to patients in need amounts to a criminal offence. It is mandatory to test every unit of donor blood for antibodies to human immunodeficiency virus (HIV-1 and HIV-2), syphilis, hepatitis C, hepatitis B and for malarial parasite. Hepatitis C virus (HCV) is an emerging infection in India and an important pathogen causing liver disease. The prevalence of HCV infection in voluntary or mixed donors has been observed to be below 2%. The high risk of chronicity of this blood-borne infection and its association with hepatocellular carcinoma underscores its public health importance. Blood transfusion and unsafe therapeutic interventions by infected needles are two preventable modalities of spread of HCV infection.

In modern blood banks, enzyme linked immunosorbent assay (ELISA) method is the recommended and preferred screening method for detecting anti-HCV immunoglobulin G (IgG) antibodies. However, many blood banks in India do not have the facilities to carry out the ELISA test for anti-HCV IgG antibodies and prefer to use “easy to perform”, “user friendly” immunochromatographic rapid screening tests instead. A pilot study was therefore conducted in healthy blood donors to study the performance of immunochromatographic (rapid) device test in the detection of anti-HCV IgG antibodies, considering ELISA method as the ‘gold standard’.

The study was carried out on 1002 blood samples collected from apparently healthy voluntary as well as replacement donors over a period of two months. All the samples were tested for anti-HCV IgG antibodies by ELISA method (Hepanostica HCV Ultra; Beijing United Biomedical Co., LTD, Wales, UK) and immunochromatographic (rapid) device test kit (SD BIOLINE HCV Standard Diagnostics, Inc., Kyongi-do Korea) simultaneously as per the manufacturer’s instructions. Considering ELISA test as gold standard, the sensitivity, specificity, positive-predictive value and negative-predictive value were calculated (Table 1).

Table 1: Performance characteristics of HCV ELISA and rapid test kits

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<thead>
<tr>
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<th>ELISA (reactive)</th>
<th>ELISA (non-reactive)</th>
<th>Total</th>
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<tbody>
<tr>
<td>Rapid (non-reactive)</td>
<td>7</td>
<td>994</td>
<td>1001</td>
</tr>
<tr>
<td>Rapid (reactive)</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>995</td>
<td>1002</td>
</tr>
</tbody>
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HCV=Hepatitis C Virus; ELISA=enzyme linked Immunosorbent Assay

The rapid immunochromatographic test was found to have a sensitivity, specificity, positive-predictive value and a negative-predictive value of 0%, 99.9%, 0% and 99.3% respectively. None of the
samples that tested reactive by ELISA could be detected by the rapid method. Failure of the rapid kits to detect HCV reactive samples may be due to inadequate coating of the antigens, nature of the antigens used or genetic heterogeneity of the virus. Most of these rapid assays use recombinant proteins from the prototype virus alone. Studies\textsuperscript{4,5} showed that variants of HCV may differ substantially in nucleotide sequence from one another and show varied geographical and epidemiological distributions.

Results of the present study showed that the sensitivity of rapid immunochromatographic test kits used for anti-HCV antibodies screening was significantly low and the rapid tests are inferior compared to ELISA. We strongly feel that rapid immunochromatographic test should not be used in blood banks for screening blood donors for HCV infection. We also feel that stringent laws need to be introduced to address this problem.

REFERENCES


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