8. Levey AS, Coresh J, Balk E, Kausz AT, Levin A, Steffes MW et al. National Kidney Foundation practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Ann Intern Med 2003;139:137-47.
9. Cortas NK, Wakid NW. Determination of inorganicnitrate in serum and urine by kinetic cadmium reduction method. Clin Chem 1990;36:1440-3.
10. Rajendra W. High performance liquid chromatographic determination of amino acids in biological samples by precolumn derivation with O-phthaldialdehyde. J Liq Chromatogr 1987;10:941-55.

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Evaluation of 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.[1] 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.[2] 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 beenobserved to be below 2%.[3] 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.[4] 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 (Hepano- stica 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

	ELISA (reactive)	ELISA (non-reactive)	Total
Rapid (non-reactive)	7	994	1001
Rapid (reactive)	0	1	1
Total	7	995	1002

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[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

1. Garg S, Mathur DR, Garg DK. Comparison of Seropositivity of HIV, HBV, HCV and syphilis in voluntary and replacement blood donors in Western India. Indian J Pathol Microbiol 2001;44:409-12.
2. Nanu A, Sharma SP, Chatterjee K, Jyoti P. Markers for transfusion-transmissible infections in north Indian voluntary and replacement blood donors: prevalence and trends 1989-1996. Vox sang 1997;73:70-3.
3. Mukhopadhya A. Hepatitis C in India. J Biosci 2008;33:465-73.
4. Kaur H, Dhanao J, Oberoi A. Evaluation of rapid kits for detection of HIV, HBsAg and HCV infections. Indian J Med Sci 2000;54:432-4.
5. Raghuraman S, Subramanium T, Abraham P, Sridharan G. Evaluation of rapid assay for HCV antibody detection. Indian J Med Microbiol 1999;7:140-1.

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