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Application of nucleic acid technology (NAT) in the diagnosis of active viral replication in HBV and HCV infections and evidence for HBV surface antigen mutants

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Introduction: The community prevalence of Hepatitis B (HBV) and hepatitis C (HCV) infections, although considered low (< 1%) in Sri Lanka based on serological markers, pose a significant health threat to patients in high risk groups. The early diagnosis of active viral infection is crucial in such situations to prevent further transmission and to enable the clinicians to initiate successful therapeutic interventions. **Objective:** This study was carried out to investigate the usefulness of polymerase chain reaction (PCR) in the diagnosis of active viral replication in HBV and HCV infections. **Methodology:** All specimens from patients with serological evidence of hepatitis B (HBV surface antigen and/or antibodies for HBV core protein) or hepatitis C (antibodies for hepatitis C core protein-Anti-HCV) and referred to the Molecular Medicine Unit from May 2005 to May 2008 were analyzed by PCR and reverse-transcription PCR (RT-PCR) for HBV DNA (n=130) and HCV RNA (n=95) respectively. **Results:** Of the 130 patients tested, 57 (44%) were positive for HBV DNA. The positive group of patients included 10 renal transplant patients, 4 multiply transfused patients, 4 paediatric patients with lymphoma, and 1 patient with cirrhosis. Six HBV DNA positive patients had negative HBsAg serology profiles indicating the possibility of surface antigen mutant strains. The HBV DNA negative patients with positive serology profiles indicate sero-converted/patients with resolved infections or false positive serology results. Of the 95 patients tested, 14 (15%) were positive for HCV RNA and included 3 paediatric patients with thalassaemia. HCV RNA negative, anti-HCV positive profiles reflect either false positive serology results (due to less specific antibody assays) or donors who have been exposed to HCV previously and subsequently resolved their infections. **Conclusions:** A major proportion of patients with serological markers for HBV have active viral infection whereas only relatively a minor proportion of patients with serological markers for HCV have active viral replication. We have also found the first possible evidence of hepatitis B surface antigen mutant strains. This underlines the importance of the nucleic acid based technology in the diagnosis and assessment of infection with or suspected to have hepatitis B or C infections. We also emphasize the importance of introducing NAT for screening donors for HBV DNA and HCV RNA to substantially lower the risk of acquiring HBV/HCV infection from a transfusion.

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