

Diagnosis of hepatitis C virus-associated chronic liver disease in India: comparison of HCV antibody assay with a polymerase chain reaction for the 5' noncoding region.

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Abstract:

The relative value of an anti-hepatitis C virus (HCV) serological assay and reverse transcriptase-nested polymerase chain reaction assays (RT-PCR) were investigated for the constant 5' putative noncoding region of HCV for the diagnosis of HCV-associated chronic liver diseases in India. One hundred fifteen patients with biopsy proven chronic active hepatitis and 140 cases of cirrhosis of the liver were investigated for anti-HCV antibody using a second generation commercial enzyme-linked immunosorbent assay (ELISA). A proportion of these patients: 42 with chronic hepatitis and 27 with cirrhosis of the liver were analysed further for HCV RNA in the serum using RT-nested PCR assay. Thirty-three (12.9%) of the 255 patients were positive for anti-HCV antibody and 23 of 69 (33.3%) patients were positive for HCV RNA in serum. Fifteen of the 33 (45.5%) anti-HCV positive patients had HCV RNA in the serum. Eight of 36 (22.2%) HCV seronegative patients tested were found with HCV RNA. This indicates that the diagnosis of HCV infection is not possible if it is based solely on the available serodiagnostic tests. Inclusion of both assays improved the diagnostic efficiency, 18.8% (13/69) were negative for all virological markers associated with HBV and HCV infection. Since a majority of the chronic liver disease patients (143/255 [56%]) were seronegative for either HBV or HCV infection, it is significant that HCV RNA was detected in 38% (8/21) of a randomly selected group from these patients. The antibody assay and PCR were compared using interclass correlation (kappa statistics). (ABSTRACT TRUNCATED AT 250 WORDS)