Comparative evaluation of the total hepatitis C virus core antigen, branched-DNA, and amplicor monitor assays in determining viremia for patients with chronic hepatitis C during interferon plus ribavirin combination therapy.

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Résumé en anglais	An assay prototype designed to detect and quantify total hepatitis C virus [HCV] core antigen (HCV core Ag) protein in serum and plasma in the presence or absence of anti-HCV antibodies has been recently developed by Ortho-Clinical Diagnostics. The aim of the study was to evaluate the sensitivity, specificity, and reproducibility of the Total HCV core Ag assay in comparison with two quantitative assays for HCV RNA: Quantiplex HCV RNA 2.0 (bDNA v2.0) or Versant HCV RNA 3.0 (bDNA v3.0) assays and the Cobas Amplicor HCV Monitor version 2.0 (HCM v2.0) test. We have studied samples of a well-characterized panel and samples from patients with chronic hepatitis C treated with interferon alone or with ribavirin. We have also compared the kinetics of HCV core Ag and HCV RNA in the follow-up of treated patients. The HCV core Ag assay exhibited linear behavior across samples from different genotypes. The coefficients of variation for intra- and interassay performance were 5.11 and 9.95%, respectively. The specificity of the assay tested in blood donors was 99.5%. Samples from HCV-infected patients showed that the correlation between the HCV core Ag and the two HCV RNA quantitative assays (bDNA and HCM v2.0) was 0.8 and 0.7, respectively. This correlation was maintained across different genotypes of HCV (r(2) = 0.64 to 0.94). Baseline HCV core Ag values were significantly lower in sustained responders to interferon (IFN) than in other groups of patients (5.31 log(10) [10(4) pg/ml] versus 5.99 log(10) [10(4) pg/ml]; P < 0.001). In patients treated with IFN or combination therapy, we found an association between a decrease of more than 2 log IU/ml in viral load, undetectable HCV core Ag, and sustained response. Among sustained responders to IFN alone or combination therapy and among relapsers after IFN alone, 84 out of 101 (83.2%) had undetectable HCV core Ag, and 76 out of 96 (79.2%) had a viral load decrease of >/=2 log IU/ml, after 1 month of treatment. In conclusion, the Total HCV core Ag assay is a new useful test for the detection of HCV viremia and the monitoring of patients treated with IFN alone or in combination with ribavirin.
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