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Performance of a highly sensitive hepatitis B surface antigen assay among chronic hepatitis B patients after hepatitis B surface antigen seroclearance

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BACKGROUND: Hepatitis B virus (HBV) persists at low replicative levels among chronic hepatitis B (CHB) patients after hepatitis B surface antigen (HBsAg) seroclearance. The performance of novel HBV serologic assays among this group of patients is undetermined. METHODS: We used a highly-sensitive HBsAg (hs-HBsAg) assay employing a semi-automated immune complex transfer chemiluminescence enzyme technique (ICT-CLEIA, Sysmex, Kobe, Japan) for the detection of HBsAg. The lower limit of detection is 0.0005 IU/mL, 100 times more sensitive than conventional HBsAg assays. We recruited CHB patients achieving HBsAg seroclearance with hs-HBsAg measured at the time of HBsAg seroclearance and 6–12 months after HBsAg seroclearance as documented by Elecsys HBsAg II (Roche Diagnostics, Branchburg, NJ). RESULTS: 75 patients (mean age 49.7 years, 76 % male, genotype B/C distribution 57.3/42.7 % respectively) were recruited, of which 25 (33.3 %) were on nucleoside analogue therapy (median duration of therapy 6.0 years). Six patient had detectable HBV DNA ([20 IU/mL) at HBsAg seroclearance; there was no detectable HBV DNA in all patients 6–12 months after HBsAg seroclearance. 59 (78.7 %) and 45 (60.0 %) patients were hs-HBsAg positive at time of HBsAg seroclearance and 6–12 months after HBsAg seroclearance respectively (median detectable levels 0.042 and 0.013 IU/mL respectively). For all 150 measurements, a positive antibody to HBsAg (anti-HBs,[10 m IU/mL) was borderline associated with a negative hs-HBsAg ($p = 0.052$). Patients with positive anti-HBs, compared to patients with negative anti-HBs, had significantly lower median hs-HBsAg levels (0.002 and 0.010 IU/mL respectively, $p = 0.019$). CONCLUSION: Serum hs-HBsAg achieved high rates of detectability among CHB patients with HBsAg seroclearance. Anti-HBs positivity was associated with lower hs-HBsAg levels. Serum hs-HBsAg could potentially assist the differentiation of occult hepatitis B patients from individuals with only past HBV exposure.