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Paper Poster Session

Hepatitis B vaccination and transmission

Evaluation of the assay for hepatitis B virus (HBV) surface antigen quantification in the laboratory diagnosis of HBV infection

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Background: Hepatitis B virus infection is a global public health problem, affecting around 2 billion people worldwide. HBV infection is a leading cause of chronic hepatitis, liver cirrhosis, and hepatocellular carcinoma. The quantitative measurement of hepatitis B surface antigen (HBsAg) monitors the progress of chronic hepatitis B, and its rapid decline may be a predictor of the efficacy of antiviral therapy. Although the measurement of serum HBV DNA is the gold standard method for viral load evaluation, the assay is expensive and time consuming, while HBsAg quantification (qHBsAg) is rapid and cost-effective. The aim of this study is to compare the results of qHBsAg and HBV DNA determination, referred to subjects with chronic hepatitis B.

Material/methods: During the 2013-2015 period, 371 plasma or serum samples of subjects attending the University Hospital of Parma (Northern Italy) were subjected to qHBsAg, by means of the ARCHITECT HBsAg assay (Abbott, Wiesbaden, Germany), with a specificity and sensitivity of 99.87% and 99.52%, respectively, as reported by the manufacturer. Of these subjects, 333 (89.8%) were subjected to HBV DNA quantification, by means of the COBAS AmpliPrep/COBAS TaqMan HBV version 2.0 assay (Roche, Mannheim, Germany).

Results: Of the 371 individuals analysed, 224 (60.4%) were males (median age of 53 ± 15.3 years) and 147 (39.6%) females (median age of 52 ± 15.3 years); 235 (63.3%) were Italians and 136 (36.7%) foreigners. The subjects aged ≥61 years (30.7%) prevailed, and 359 (96.8%) were positive for qHBsAg. The comparison of the mean HBsAg level of the 359 positive subjects with those of different derived subpopulations evidenced higher HBsAg levels for HBeAg-positive subjects (3.1%; $P < 0.0001$), subjects infected with genotype D of HBV (3.6%), and females (39%). Conversely, males (61%) and human immunodeficiency virus type 1 (HIV 1) co-infected subjects (3.6%) showed lower HBsAg levels. Moreover, HBsAg levels decreased with age, with significant differences for subjects aged ≤30 ($P < 0.0001$) and ≥51 ($P < 0.05$) years. The accordance among the results of qHBsAg and HBV DNA determination was of 69.7% (232/333 samples) and the qHBsAg assay sensitivity of 99.6% (227/228 samples).

Conclusions: This study assesses that many factors may influence HBsAg levels, such as sex, age, HIV co-infection, HBeAg status, and HBV genotype. Although the sensitivity of qHBsAg assay is high, the discrete accordance with HBV DNA determination envisages that HBsAg measurement cannot be a reliable substitute, but a complementary assay, which allows better chronic HBV infection monitoring.