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中文題目

血清表面抗原定量濃度在接受長效型干擾素治療之e抗原陰性慢性B型肝炎病患之預測角色

英文題目

Predictive Role of Quantitative Serum HBsAg Level in HBeAg-Negative Chronic Hepatitis B Patients Undergoing Peginterferon Therapy

內　　文

背景/Background :

The predictive role of early quantitative serum HBsAg level in chronic genotype B or C infected HBeAg-negative patients undergoing peg-interferon (Peg-IFN) alfa-2a therapy is unclear.

方法/Methods :

One hundred and four consecutive HBeAg-negative chronic hepatitis B patients receiving 48 weeks of Peg-IFN alfa-2a therapy and 48 weeks of post-treatment follow-up were retrospectively/prospectively enrolled from Nov 2004 to Aug 2012. Serum HBsAg and HBV DNA levels were quantified using the Abbott Architect HBsAg QT assay (dynamic range, 0.05-250.0 IU/mL) and the Cobas Amplicor HBV

Monitor Test (LLOD: 312 copies/mL), or Cobas Taqman real-time PCR assay (LLQ: 70 copies/mL), respectively, at baseline, 12, 24, and 48 weeks during treatment, and at 24 and 48 weeks after the end of therapy. Univariate and multivariate logistic regression models were used to examine the crude and adjusted effects of baseline and on-treatment serum HBsAg and HBV DNA levels on the therapeutic outcomes. The predictive value of each of these factors was examined based on the analysis of AUROC.

結果/Results :

The baseline features were: median age: 41 years, 88% men, 80%/20% genotype B/C, median ALT: 86 IU/L, HBV DNA: 6.66 $\log_{10}$copies/mL, and HBsAg: 3.12 $\log_{10}$IU/mL. At the end of treatment, 88% and 68% of patients achieved HBV DNA <10,000 and <312 copies/mL, respectively. At 48 weeks post-treatment, 27% and 9% of patients had HBV DNA <10,000 and <312 copies/mL, respectively. By multivariate analyses, the serum HBsAg and HBV DNA levels at baseline, treatment weeks 12, 24 and 48, and the decline from baseline in HBsAg level at treatment weeks 24 and 48 were significantly associated with the achievement of HBV DNA <10,000 copies/mL at 48 weeks post-treatment. The serum HBsAg levels at baseline, treatment weeks 12, 24 and 48 were significantly associated with the achievement of HBV DNA <312 copies/mL at 48 weeks post-treatment. The serum HBsAg level at week 12 (AUC: 0.66 and 0.78 respectively) or 24 (AUC: 0.66 and 0.78 respectively) had the highest predictive value for achieving HBV DNA <10,000 and <312 copies/mL at 48 weeks post-treatment, respectively. A serum HBsAg cut-off of 120 IU/mL at week 12 gave a PPV/NPV of 65%/82% and 30%/96%, for predicting HBV DNA <10,000 and <312 copies/mL at 48 weeks post-treatment, respectively. A serum HBsAg cut-off of 80 IU/mL at week 24 gave a PPV/NPV of 60%/82% and 32%/98%, for predicting HBV DNA <10,000 and <312 copies/mL at 48 weeks post-treatment, respectively.

結論/Conclusions :

Serum HBsAg level at week 12 of therapy serves best to predict treatment response (HBV DNA <10,000 copies/mL at 48 weeks post-treatment) but sub-optimally as an early stopping rule in genotype B or C infected HBeAg-negative patients undergoing Peg-IFN therapy.