学位の種類	博士（医学）
報告番号	甲第１９８６号
学位記番号	第１３９７号
氏名	鈴木 孝典
授与年月日	令和５年 ９月 25 日
学位論文の題名	Clinical usefulness of a novel high-sensitivity hepatitis B core-related antigen assay to determine the initiation of treatment for HBV reactivation (B 型肝炎再活性化に対する治療導入を決定する新規高感度 B 型肝炎コア関連抗原測定法の臨床的有用性) Journal of Gastroenterology, 57(7): 486-494, 2022
論文審査担当者	主査： 奥野 友介 副査： 瀧口 修司, 飯田 真介

Abstract

Backgrounds: Hepatitis B virus (HBV) reactivation during and after systemic chemotherapy is a severe problem and sometimes leads to fulminant hepatitis. Therefore, monitoring patients for the early detection of HBV reactivation is necessary. A fully automated, novel, high-sensitivity hepatitis B core-related antigen assay (iTACT-HBcrAg) has been developing. The purpose of this study is to evaluate the efficacy of measuring HBcrAg, using that assay, to diagnose HBV reactivation in a multi-center setting, compared with ultra-high-sensitivity HBsAg (iTACT-HBsAg) and HBV DNA assays. Methods: Forty-four patients with HBV reactivation from 2008 to 2020 were enrolled in four hospitals. Serial serum specimens from the patients were assessed retrospectively for their HBcrAg levels by iTACT-HBcrAg (lower limit of detection; 2.0 log U/mL) and HBsAg levels by iTACT-HBsAg (lower limit of detection; 0.0005 IU/mL); these were compared to the HBV DNA levels. HBV reactivation was defined as detection of serum HBV DNA, including unquantifiable detection. Results: At HBV reactivation and/or thereafter, HBV DNA levels were quantified (≥ 1.3 log IU/mL) in the sera of 27 patients, and were below the level of quantification (<1.3 log IU/mL) in the sera of 17 patients. Of the 27 patients with HBV reactivation and whose serum HBV DNA was quantified, the sera of 26 and 24 patients (96.3% and 88.9%) were positive by iTACT-HBcrAg and iTACT-HBsAg, respectively. HBcrAg was detectable by iTACT-HBcrAg before HBV DNA was quantifiable in 15 of the 27 patients. Of the 11 patients with HBV reactivation and undetectable HBcrAg by iTACT-HBcrAg at HBV reactivation and/or thereafter, 10 had unquantifiable HBV DNA and none developed HBV reactivation-related hepatitis. Conclusions: The iTACT-HBcrAg assay is useful for monitoring HBV reactivation to determine the initiation of treatment with nucleos(t)ide analogues.