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Using clinical databases to verify the impact of Japanese regulatory agency alerts: Hepatitis B testing behavior after an alert regarding risk of viral reactivation

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Measures of the effectiveness of risk minimization activities are necessary for the appropriate use of drugs, and clinical databases are a low-cost method of quickly producing such results. To explore the secondary application of clinical databases in verifying the impact of risk minimization activities, specifically whether such databases could be used to identify changes in hepatitis B virus testing behavior after an alert from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. Patient data from Dec-1, 2010 to Nov-30, 2012 were extracted from the Medical Data Vision clinical database. The percentages of patients tested for hepatitis B virus DNA (HBV-DNA), hepatitis B surface antigen (HBsAg), and HBs antibody (HBsAb)/hepatitis B core antibody (HBcAb) were compared 1 year before (consecutive 6-month periods A and B) and 1 year after (consecutive 6-month periods C and D) a PMDA alert regarding viral reactivation in patients receiving immunosuppressive agents. Data for 9,866 patients in the clinical database were analyzed. After the PMDA alert, the percentage of patients tested for HBV-DNA linearly increased in periods A to D: 4.70% (n=262/5571), 5.78% (n=330/5710), 6.52% (n=398/6101), and 7.59% (n=479/6315). However, no changes were observed in the rates of HBsAg and HBcAb/HBsAb testing (around 50% and 70%, respectively). Overall testing rates appeared to differ depending on disease and drug type. These findings suggest that the PMDA alert was effective at recommending HBV-DNA testing. This secondary application of clinical databases may be effective for verifying the impact of risk minimization activities.

Biography

Yukio Udagawa graduated from the College of Pharmacy, Nihon University. He is a PharmD Specialist and Safety Science Leader of Chugai Pharmaceutical Co., Ltd., Tokyo, Japan. He has published some papers in reputed journals and has been serving as a regular member of the Japanese Society of Dialysis Therapy.

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