Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/Adverse Event Information

Medical Safety Information

No.171, February 2021

Reactivation of Hepatitis B Due to Immunosuppression/Chemotherapy

Thirteen cases have been reported in which patients were affected by the reactivation of the hepatitis B virus (HBV) due to immunosuppression/chemotherapy as a result of the failure to carry out screening or monitoring, or the halting of administration of nucleos(t)ide analogue preparations (information collection period: from January 1, 2017 to December 31, 2020). This information was compiled on the basis of the content featured in the Recurrence of Events and Occurrence of Similar Events section of the 48th Quarterly Report.

Cases have been reported in which patients were affected by the reactivation of HBV due to immunosuppression/chemotherapy.

Examination/Treatment Process	Factors	Main Background Factors
HBs antigen screening	Not carried out	HBs antigen screening was not carried out before starting immunosuppressants
		HBs antigen screening was not carried out, because the patient had a history of using immunosuppressants under their previous physician
HBc antibody/HBs antibody test	Not carried out	The HBc antibody/HBs antibody tests conducted for those who test negative for HBs antigen in screening were not carried out
HBV DNA quantitative test		
HBV DNA quantitative level & AST/ALT monitoring	Not carried out	The HBV DNA quantitative test was omitted due to inadequate checks of the outpatient blood collection order
		Nobody noticed that the HBV DNA quantitative test had not been carried out, as the hospital had no mechanism for checking regular monitoring
Administration of nucleos(t)ide analogue	Administration halted	Administration was not continued, because the department of gastrointestinal medicine was not contacted at the time of discharge from the otorhinolaryngology department

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Case 1

The patient had been being prescribed immunosuppressants to treat rheumatoid arthritis since a few years earlier, but had not undergone testing to identify whether HBs antigen was present prior to starting the immunosuppressants. When the patient was admitted for cardiac catheterization, their blood test revealed high HBs antigen levels, so the physician consulted the department of hepatobiliary and pancreatic medicine. After a thorough examination, the patient was diagnosed with hepatitis B and administration of a nucleos(t)ide analogue was started.

Case 2

The patient had been using immunosuppressants since a bone marrow transplant for acute lymphoblastic leukemia. At an outpatient consultation, the physician found the patient to have liver damage. After checking, the physician found a pattern consistent with prior HBV infection and realized that the HBV-DNA quantification tests usually conducted every month to three months had not been carried out. After a thorough examination, the patient was diagnosed with acute hepatitis due to reactivation of HBV and was admitted to hospital as an emergency.

Preventive measures taken at the medical institutions in which the events occurred

- **Ensure that all the institution's medical staff are aware that immunosuppression/ chemotherapy can reactivate HBV and inform them of the Guidelines for the Management of Hepatitis B Virus Infection.**
- **Consult a specialist clinical department if a patient starting immunosuppression/ chemotherapy tests positive for HBs antigen.**

The measures above are examples. Please consider initiatives suitable for your own facility.

Version 3.3 (January 2021) of the Guidelines for the Management of Hepatitis B Virus Infection edited by the Drafting Committee for Hepatitis Management Guidelines established by the Japan Society of Hepatology contains guidelines for the prevention of hepatitis B virus reactivation in patients receiving immunosuppressive therapy or chemotherapy.

Key Preventive Measures

- **Clarify which of the institution's drugs require caution in respect of the reactivation of HBV and consider creating an HBs antigen screening mechanism.**

(Comprehensive Evaluation Panel)

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of the "Comprehensive Evaluation Panel" to prevent the occurrence and recurrence of medical adverse events. See the Project website for details.
https://www.med-safe.jp/

* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.

* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

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