Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.33, August 2009

Extravascular leakage of gabexate mesilate

Eight cases of requiring subsequent treatment because of extravascular leakage occurred during administration of gabexate mesilate to the patient, have been reported. Among these, six cases of using at a concentration that exceeded the recommendation listed in the "precautions regarding use and dose" in the package insert, have been reported. (information collection period, from January 1, 2006 to June 30, 2009; the information is partly included in "Medical Adverse Event Information to Be Shared" in the 3rd Quarterly Report)

When gabexate mesilate is administered in high concentration, injury may occur to the inner walls of the blood vessels.

Gabexate mesilate products

Agalit 100	Panabate 100 for inj. Panabate 500 for inj.
Arodate 100mg Arodate 500mg	Probitor for inj. 100mg Probitor for inj. 500mg
FOY 100 FOY 500	Mechuroseito 100mg Mechuroseito for injection 500mg
Sokusidon	Reminaron 100mg Reminaron 500mg

◆ Refer to the package insert regarding the use of gabexate mesilate.

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Case 1

The physician was not aware of the use precautions regarding the concentration of Panabate and administered approximately 2% concentration of "Panabate 2000mg + 5% glucose solution 100mL" from the right forearm of the patient. The next day, extravascular leakage and an ulcer approximately 2 × 2.5cm in size in the right forearm were observed. Ten days later, necrosis developed in the right forearm and the patient received a skin grafting.

Case 2

An approximately 3% concentration of "FOY 1500mg + Normal saline 50mL" was administered to the patient from the dorsum of the hand for several days. During the administration, although extravascular leakage was observed on the dorsum of the hand, the swelling was slight and it was left for observation. Eighteen days after the administration, the right forearm of the patient swelled. Phlegmon caused by bacterial infection was suspected and treatment was initiated, but the condition did not improve. Later, the condition was diagnosed by a dermatologist as injury to the blood vessels and soft tissues due to the administration of FOY.

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

- **When administering gabexate mesilate, the drug will be administered through the central vein whenever possible.**
- **When administering gabexate mesilate through periferal veins, the concentration of the infusion shall be 0.2% or less (50mL or more of solution per 100mg of the drug).**

* 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 "Comprehensive Evaluation Panel" to prevent occurrence and recurrence of medical adverse events. See quarterly reports and annual reports posted on the Japan Council for Quality Health Care website for details of the Project. http://www.med-safe.jp/

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

* This information is neither for limiting the discretion of healthcare providers nor for imposing certain obligations or responsibilities on them.

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