Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.35, October 2009

Respiratory suppression due to Remifentanil (Ultiva) remained in intravenous infusion line

Three cases of respiratory suppression due to unintentional administration of Remifentanil (Ultiva) remaining in the intravenous line after surgery under general anesthesia have been reported (information collection period, from January 1, 2006 to August 31, 2009; the information is partly included in "Medical Adverse Event Information to Be Shared" in the 17th Quarterly Report).

Cases of respiratory suppression due to unintentional administration of Ultiva remaining in the intravenous line through which the administration of Ultiva had been stopped and another drug followed, have been reported.

◆ Initial date of marketing in Japan is January 2007.

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Case 1

After Ultiva was administered to a patient through an intravenous line of the left upper limb at the rate of 0.2μg/kg/min in the operation room, Hepalin lock was conducted for the line by flushing small amount of normal saline with Hepalin. When an infusion resumed through the locked intravenous line after the patient returned to the ward, the patient suddenly suffered respiratory arrest.

Case 2

The anesthesiologist finished continuous administration of Ultiva at the end of the surgery, and extubated the endotracheal tube. Afterwards, the anesthesiologist noticed that the infusion bottle was empty, and changed it to the new one. While the patient was transfered to the recovery room, the anesthesiologist noticed that the patient was unconscious and in a state of respiratory arrest. Manual artificial respiration was initiated immediately and the patient regained consciousness. Rapid overdose of Ultiva remaining in the infusion line due to the infusion bottle replacement was supposed to be the cause of the respiratory arrest.

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

After Ultiva administration is finished, anesthesiologist shall confirm that Ultiva does not remain in the infusion line, and have the patient leave the room.

* 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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