

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.51, February 2011

Insufficient knowledge of the administration status for warfarin potassium and blood coagulability

Five cases of bleeding after invasive treatment, due to insufficient knowledge of information regarding the administration status and blood coagulability of patients taking warfarin potassium, have been reported (Information collection period: from January 1, 2007 to December 31, 2010; the information is partly included in "Individual Theme Review" (p.140) in the 20th Quarterly Report).

Cases of unexpected bleeding after invasive treatment due to insufficient knowledge of the administration status and blood coagulability of patients taking warfarin potassium, have been reported.

	Administration of warfarin potassium	Amount of warfarin potassium administered	blood coagulability data	Number of cases
Knowledge of	\checkmark	~		3
information ✓ : known	~			1
—: not known	—	<u> </u>	—	1

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Case

The patient who suspected of having a cancer of the tongue was taking 3mg/day of Warfarin for lower extremity varicose veins of the legs. The physician carried out a blood examination for tissue biopsy. When performing the biopsy, the physician checked the blood examination results on the electric medical record, the value of the blood coagulability examination was shown "under exam." However, the physician still performed the biopsy, and released the patient after confirming that bleeding had stopped. Three hours later, the patient observed bleeding inside the mouth, and return to the hospital as emergency room. Hematoma from the tongue and submandibular region to the neck was observed, and endotracheal intubation and lingual artery embolization were performed.

Preventive measures taken at the medical institution in which the event occurred.

Before performing invasive treatment, thorough confirmation of the status of the administered medicine regarding coagulation and the examination results regarding blood coagulability shall be carried out.

Warfarin potassium products (as of December 31, 2010)

Arefarin tablets 1mg

• Warfarin K Fine Granules 0.2% "NS" • Warfarin Potassium Tablets 0.5mg / 1mg "TOWA" • Warfarin K Fine Granules 0.2% "YD" • Warfarin Potassium Tablets 0.5mg / 1mg / 2mg "HD"

- Warfarin 0.5mg / 1mg / 5mg • Warlin 0.5mg / 1mg
 - - Warfarin Potassium Tablets 1mg
- There are other medicines which effect blood coagulability besides warfarin potassium.

Complementary comment by the Comprehensive Evaluation Panel

When treating of patients undergoing an anticoagulant, please refer to "IV. Supplemental 2. Handling during Tooth Removal and Surgery" in the "Guidelines for management of anticoagulant and antiplatelet therapy in cardiovascular disease (JCS2009)" published by The Japanese Circulation Society, etc.

Refer to the website of The Japanese Circulation Society "Guidelines for Diagnosis and Treatment of Cardiovascular Diseases" (http://www.j-circ.or.jp/quideline/index.htm)

- * 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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