Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

Medical Safety Information

No.58, September 2011

Rupture of the subcutaneous port and catheter

Twenty-four cases of catheter rupture in patients who have subcutaneous port, have been reported (information collection period: from January 1, 2007 to July 31, 2011; the information is partly included in “Individual Theme Review” (p.101) in the 21st Quarterly Report).

As signs of rupture of the subcutaneous port and catheter, obstruction and pain in the region at starting injection, inadequate infusion flow rate during injection, extravasation, and swelling, have been reported.

Period	Signs of the catheter rupture case	Number of cases
Starting injection	Blockage of the port (reverse blood flow cannot be confirmed, etc.)	4
	Pain (port area, region of insertion, etc.)	4
	Extravasation (region of insertion)	2
	Other (discomfort, etc.)	3
During injection	Inadequate infusion flow rate	7
	Extravasation (subcutaneous, port area, around clavicle, etc.)	6
	Swelling (port area, etc.)	4
	Pain (right subclavicular, right shoulder)	2
	Other (redness, etc.)	2
Other	Pain (right subclavicular or chest, right chest pain when flushed)	3

◆ Among these reported cases, there were cases with multiple signs were reported, and cases where the signs were unclear.

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Case

Medicine was administered from an implanted central venous catheter (CV port) using an infusion pump, for chemotherapy. After two hours, swelling around the CV port and subcutaneously leaking of the medicinal solution were noticed. Rupture of the CV port was confirmed by chest X-ray. The ruptured catheter in the cardiac was removed under angiography in the department of radiology.

The ministry of Health, Labour and Welfare has issued notification regarding revised directions in the attached document related to subcutaneous port and catheter.

○ Issued by the Safety Division of the Pharmaceutical and Food Safety Bureau, 0525-1, the General Affairs Division of the Pharmaceutical and Food Safety Bureau, 0525-1, May 25, 2011

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

- **Explain the risk and signs of catheter rupture to the patient when explaining the insertion of a subcutaneous port.**
- **When signs such as inadequate infusion flow rate, extravasation, obstruction or pain occur, consider the possibility of a catheter rupture.**

* 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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