PMDA Alert for Proper Use of Medical Devices

Pharmaceuticals and Medical Devices Agency

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Bleeding Caused by the Use of IMPELLA Circulatory Assistance Pump Catheter

Cases of bleeding from the insertion site when using IMPELLA circulatory assistance pump catheter have been reported. (Please see the next page.)
Precautions for puncture techniques and the management after placement are stated in package inserts and instruction manuals. In order to prevent serious bleeding, please check the latest package inserts and instruction manuals, and pay close attention to the following points.

(1) Evaluation of vascular access
Check the access method to avoid or reduce the risk of complications (bleeding, etc.) at the puncture site during the period of circulatory assistance.

(2) Operation of peel-away introducer
Slide the peel-away introducer completely out of the body prior to peeling it away.

(3) Securing the placement sheath
The angle of the placement sheath may vary due to changing the body position and patient care, etc. Periodically confirm that it is secured at the same angle as the puncture angle.

(4) Anticoagulation therapy
Because the recommended activated clotting time (ACT) values at the time of insertion (250-500 seconds) and after insertion (160-180 seconds) are different, please measure the ACT value periodically.

If a malfunction of a medical device or serious health hazard occurs, please promptly report this to the manufacturer or PMDA.

Specific cases

Disclaimer
This information document states the general precautions, and it is not intended to question the appropriateness of the treatment plan in each case. Each treatment plan should be determined through discussions between the patient and the physician considering the condition of each patient.

Evaluation of vascular access
When the subclavian artery was evaluated by plain CT, it had calcification. When insertion was attempted, it became difficult, and insertion was performed from the femoral artery. Afterwards, bleeding was observed from the subclavian artery originally planned for insertion.

Operation of introducer
When removing a peel-away introducer, bleeding was observed at the insertion site. It was peeled away before being completely removed from the vessel.

Surgical procedure and adjustment of insertion securing angle
Continuous bleeding from the insertion site was observed since the start of circulatory assistance. As a result, surgical suturing, adjustment of insertion securing angle of IMPELLA, and blood transfusion were performed.

Extension of ACT
Bleeding from the insertion site was observed 4 days after the start of circulatory assistance, and a blood transfusion was performed. The ACT at the time of bleeding was approximately 400 seconds.

[Additional information]

The number of reported cases of serious bleeding in 2017-2021

Type of devices	2017	2018	2019	2020	2021
IMPELLA 2.5	0	13(8)	37(26)	7(5)	5(5)
IMPELLA CP SmartAssist (including CP)	–	–	12(8)	74(69)	83(82)
IMPELLA 5.0	0	9(3)	11(5)	8(5)	10(5)

*Bleeding at the insertion site is shown in the parentheses.

About this information
*"PMDA Alert for Proper Use of Medical Devices" communicates to healthcare providers with clear information from the perspective of promoting the proper use of medical devices. The information presented here includes such cases where the reporting frequencies of similar reports have not decreased despite relevant alerts provided in package inserts, among medical device failure /infection cases reported in accordance with the PMD Act.

*We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future

*This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided to promote the proper use of the medical devices.

Access to the most up to date safety information is available via the PMDA medi-navi.

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