October 8, 1999

Complications Related to the Use of Vascular Hemostasis Devices

Dear Colleague:

I am writing to inform you of adverse events related to the use of vascular hemostasis devices. These devices provide an alternative to manual compression in achieving hemostasis following percutaneous femoral arterial punctures in patients undergoing diagnosis and treatment for cardiovascular disease. Reported complications related to these devices include hematoma, retroperitoneal bleed, pseudoaneurysm, late bleeding, and infrequently, death.

Reports

Since 1996, FDA has received reports of adverse events, including deaths, concerning closure devices. In one case, a patient, who had previously been treated with a vascular hemostasis device, suffered an acute myocardial infarction. During the ensuing catheterization, the hemostasis device was dislodged, necessitating surgical intervention. In another case, following closure with a vascular hemostasis device, the patient was discharged only to return days later with bleeding from the groin. This patient then required surgery to repair a ruptured pseudoaneurysm.

Complications can also occur when manual compression is used to achieve hemostasis. Review of the literature does show that the types of complications associated with manual compression and vascular hemostasis devices are similar. After analyzing the specific circumstances that led to the adverse events reported for vascular hemostasis devices, we believe that the following recommendations may be helpful in minimizing adverse events relating to the use of these devices.

Recommendations

Manufacturers' instructions and recommendations may vary for individual vascular hemostasis devices. In general, to avoid complications when using vascular hemostasis devices, we recommend that you carefully follow the device manufacturer's warnings, precautions, and instructions regarding patient selection and device use.

In addition, we offer the following specific recommendations:

- Do not use vascular hemostasis devices to treat patients with suspected double wall punctures, as punctures of the posterior wall are not closed with these devices.

- Carefully weigh the risk of bleeding at the puncture site against the benefits of using a vascular hemostasis device when treating patients with bleeding disorders or patients medicated with platelet glycoprotein IIb/IIIa receptor inhibitors.

- Carefully monitor the groin puncture site to minimize the occurrence of complications with vascular hemostasis devices.

- Special attention should be paid to any post-procedure patient-management instructions or ambulation recommendations for the specific vascular hemostasis device used.

Reporting adverse events to FDA

FDA is interested in additional data on adverse events involving the use of hemostasis devices. Healthcare providers employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facility. All other providers may submit their reports to MedWatch, FDA's voluntary reporting program. The reports can be submitted by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; via the MedWatch web site at www.fda.gov/medwatch; or by mail to MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, Maryland 20852-9787.

Getting more information

If you have questions regarding this letter, please contact the Issues Management Staff, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

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Sincerely yours,

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