FDA In Brief: FDA provides new information on risks for patients with endovascular grafts based on real-world data as the agency continues to monitor postmarket safety of these devices

October 28, 2019

Media Inquiries

Brittney Manchester (mailto:brittney.manchester@fda.hhs.gov)
301-796-1026

"Leaking of blood, or endoleaks, are a risk for patients who have endovascular grafts implanted to treat an enlargement of the aorta, known as abdominal aortic aneurysm. As part of our work to ensure patients and providers are aware of these risks, we've continued our ongoing efforts to evaluate information from several sources, including endovascular graft system manufacturers and real-world data, regarding the risks associated with a serious type of endoleak related to various aortic endovascular graft systems indicated for the treatment of abdominal aortic aneurysms, called a Type III endoleak. We've previously communicated about the greater risk of a Type III endoleak occurring with the Endologix AFX with Strata device. We want patients and health care providers to be aware of new information that suggests there may also be a higher than expected risk of Type III endoleaks occurring with the use of Endologix AFX with Duraply and AFX2 endovascular grafts," said Bram Zuckerman, M.D., director of the Office of Cardiovascular Devices in the FDA's Center for Devices and Radiological Health. "Real-world data, collected in electronic health records, registries and administrative claims data, provides new insights into the performance and clinical outcomes associated with medical device use, which is important to our efforts to protect and promote the public health, especially as we better understand and evaluate the available evidence on postmarket safety of devices. While we continue our evaluation on Endologix AFX endovascular grafts, we want to emphasize the importance of, at least yearly, lifelong follow-up visits for all patients who have any Endologix AFX endovascular graft. This way patients and their doctors can ensure the grafts are working properly."

Today, the U.S. Food and Drug Administration issued a safety communication (/medical-devices/safety-communications/update-risk-type-iii-endoleaks-use-endologix-afx-endovascular-aaa-graft-systems-fda-safety) providing new information about its evaluation of the risk of blood continuing to leak into an aneurysm (an abnormal widening of an artery due to weakness in the wall of the blood vessel), called a "Type III endoleak," when AFX endovascular grafts (flexible fabric tubes permanently implanted inside the largest blood vessel), made by the manufacturer Endologix, are used for the treatment of abdominal aortic aneurysm (AAA). There are three versions of the AFX endovascular graft made by Endologix that are approved by

the FDA: AFX with Strata, AFX with Duraply, and AFX2. In June 2018, the FDA communicated (/medical-devices/letters-health-care-providers/update-type-iii-endoleaks-associated-endovascular-graft-systems-letter-health-care-providers) about the greater risk of Type III endoleaks occurring with the Endologix AFX with Strata endovascular graft. Today's safety communication is being released because the FDA evaluated new information from recent real-world data, published in a conference abstract (https://www.journalacs.org/article/S1072-7515(19)31187-1/fulltext) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), suggesting that there may also be a high risk of Type III endoleaks occurring with the use of the two other types of AFX endovascular grafts – AFX with Duraply and AFX2.

The FDA recognizes that a wealth of real-world data (/science-research/science-and-research-special-topics/real-world-evidence) covering medical device experience exists and is routinely collected in the course of patient treatment and management. The FDA uses this data to monitor postmarket safety and adverse events and also communicates to the public any updated risks to medical devices, such as today's communication about Type III endoleaks reported with AFX endovascular grafts.

In the safety communication issued today, the FDA explains that endoleaks can occur after repair with any endovascular graft and typically do not result in symptoms. If left undetected and without treatment, a Type III endoleak may lead to expansion and rupture of the AAA resulting in serious patient injury, including death. Therefore, the FDA strongly recommends, at least yearly, lifelong follow-up visits for all patients implanted with any Endologix AFX endovascular grafts (AFX with Strata, AFX with Duraply or AFX2) with their doctor to ensure the devices are working properly.

The FDA and Endologix continue to work together to provide further instructions in the labeling for all AFX endovascular grafts regarding Type III endoleaks.

Related Information

- FDA: Endologix, Inc. Recalls AFX Endovascular AAA Systems Due to Risk of Type III Endoleaks (/medical-devices/medical-device-recalls/endologix-inc-recalls-afx-endovascular-aaa-systems-due-risk-type-iii-endoleaks)
- FDA: UPDATE on Type III Endoleaks Associated with Endovascular Graft Systems – Letter to Health Care Providers (/medical-devices/letters-health-care-providers/update-type-iii-endoleaks-associated-endovascular-graft-systems-letter-health-care-providers)

- FDA: Type III Endoleaks Associated with Endovascular Graft Systems - Letter to Health Care Providers (/medical-devices/letters-health-care-providers/type-iii-endoleaks-associated-endovascular-graft-systems-letter-health-care-providers)
- FDA: Real-World Evidence (/science-research/science-and-research-special-topics/real-world-evidence)

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