Research guides FDA action on common medical device

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The largest blood vessel in the body, the abdominal aorta, sends freshly oxygenated blood to the rest of the body. Each year, about 200,000 adults in the United States are diagnosed with an abdominal aortic aneurysm (AAA), a swelling and/or potentially fatal rupture of this crucial blood vessel that occurs when the vessels' walls weaken. Age, high blood pressure and smoking are among the risk factors.

Proceduralists can repair aortic aneurysms by reinforcing the weakened aorta with a device called a stent graft. This repair had previously required accessing the aorta via open surgery. In recent years, endovascular aneurysm repair (EVAR)—a minimally-invasive procedure in which a folded and compressed stent graft device is inserted through an artery in the groin, threaded up to the aorta guided by X-ray imagery, and deployed to wrap around the aneurysm—has become the mainstay in treatment of AAA. The less invasive procedure carries fewer in-hospital risks and lends itself to shorter recovery times.

However, limited long-term data exists to assess aortic stent graft outcomes as new device designs have come to market.

In a retrospective cohort study of Medicare beneficiaries who underwent aortic stent grafting, researchers from the Smith Center for Outcomes Research at Beth Israel Deaconess Medical Center (BIDMC) were commissioned by the Food and Drug Administration (FDA) to compare the long-term outcomes of a specific endograft device type with comparative devices on the market.

As part of the SAFE-AAA Study—BIDMC-led and designed in conjunction with the FDA—the researchers evaluated the safety of

newer unibody aortic stent grafts compared with other, non-unibody FDA-approved endograft devices.

The team demonstrated that the both historic and newer unibody endografts failed to outperform the non-unibody devices through a median follow up period of 3.4 years. The findings, which appear in the journal *Circulation*, support instituting a longitudinal surveillance program for monitoring safety events related to aortic stent grafts.

"There was a suggestion of persistent harm associated with unibody devices compared with non-unibody devices," said Eric A. Secemsky, MD, MSc, director of Vascular Intervention at BIDMC and principal investigator of SAFE-AAA. "In the SAFE-AAA Study, the unibody endografts failed to meet noninferiority compared with non-unibody endografts. Our study provides an important example of how real-world data can be used to monitor the safety of products already on the market, and help support regulatory decision making."

Secemsky and colleagues looked at data from 87,163 Medicare beneficiaries who underwent aortic stent grafting at more than 2000 U.S. hospitals between 2011 and 2017. Following these patients' outcomes for a median period of 3.4 years, the researchers looked at mortality from all causes after endovascular stent grafting, whether patients' aneurysms ruptured after their procedures and whether patients needed secondary intervention after their procedures.

The team found that at least one of these conditions occurred in 74 percent of unibody device-treated patients versus 65 percent of non-unibody device-treated patients. In a subgroup of patients who underwent the procedure more recently—to correspond to the market release of the newest unibody endograft—the incidence of the end-point conditions was 38 percent among unibody device-treated patients, versus 33 percent among non-unibody device-treated patients.

"The SAFE-AAA analysis evaluating unibody systems to comparator devices confirmed safety issues associated with unibody endografts but also suggests potential concerns with the newest iterations of the devices," said Secemsky, who is also an assistant professor of medicine at Harvard Medical School. "Because EVAR has become the dominant intervention to treat AAA, it is important that the endograft device class as a whole be closely scrutinized for adverse safety events. Especially with concerns over specific device designs, enhanced surveillance programs can greatly improve the understanding of device safety."

As a result of the SAFE-AAA Study's findings, in conjunction with previous studies and device safety data, the FDA has now approved and updated a device label that includes the possible long-term risks associated with certain unibody EVAR devices. They have also recommended that healthcare providers consider using alternative EVAR devices when possible and required the manufacturer to perform a long-term post market safety study.

More information: Eric A. Secemsky et al, Comparison of Unibody and Non-Unibody Endografts for Abdominal Aortic Aneurysm Repair in Medicare Beneficiaries: The SAFE-AAA Study, *Circulation* (2023). DOI: 10.1161/CIRCULATIONAHA.122.062123

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