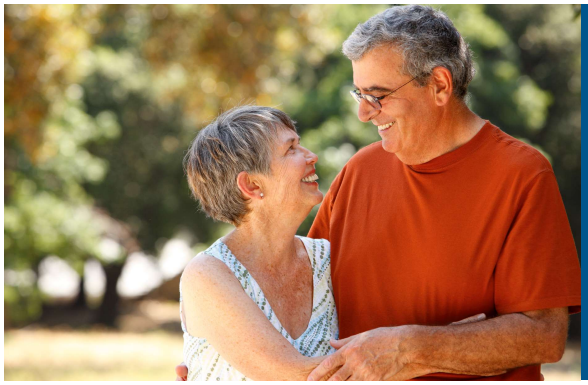
Medical Device Surveillance and Assessment (MDSA) | Newsletter



Risk for Surgical Interventions Following Endovascular Aneurysm Repair with Endologix AFX or AFX2 Endovascular AAA Systems Compared with other Devices

Medical device researchers and vascular surgeons conducted a matched cohort study using data from our Endovascular Stent Graft Registry to evaluate the risk for 90-day returns to care and long-term subsequent surgical interventions after primary endovascular aneurysm repair (EVAR) with an Endologix AFX Endovascular AAA System compared with three other high-volume endograft devices.

> This study is a good example of the importance of lifelong monitoring of EVAR procedures. With information from the registry, we identified devices that require more rigorous surveillance compared to others leading to customized device specific post-operative image surveillance for our patients.
>
> –Robert Chang, MD, Department of Vascular Surgery, The Permanente Medical Group, South San Francisco, CA | Study Author

Study Details

The treatment group included patients who received an Endologix AFX or AFX2 device (n = 470). Patients who received one of three other high-volume endograft devices used within the health care system comprised the eligible comparison group (n = 2122). These patients were 2:1 propensity score matched without replacement to patients who received an Endologix device based on a number of patient and procedural characteristics.

The final matched study sample included 470 patients who received an Endologix AFX or AFX2 device and 940 patients who received a different high-volume device. Compared with the other devices, AFX/AFX2 had a higher risk for:

- Type III endoleak (hazard ratio [HR], 38.79; 95% confidence interval [CI], 14.51-103.67)
- Revision surgery >1 year after the primary EVAR (HR, 4.50; 95% CI, 3.10-6.54)
- Rupture (HR, 6.52; 95% CI, 1.73-24.63)
- Aneurysm-related mortality (HR, 2.43; 95% CI, 1.32-4.47)

Practice Considerations

Patients who have received Endologix AFX systems devices should be monitored closely after EVAR. Device selection is at the discretion of the operating surgeon and can affect outcomes for patients following their EVAR. Understanding device performance can help surgeons in selecting best performing devices to prevent adverse outcomes and improve patient care.