VASCULAR LITERATURE HIGHLIGHTS

Study Evaluates Feasibility of Postmarket Surveillance Data to Assess Device Safety Using EVAR Device Identifiers and Structured Data

In an article published online in *JAMA Internal Medicine*, Wang et al found that although postmarket surveillance data can be used to assess medical device safety, there are challenges such as lack of unique device identifiers (UDIs) and insufficient structured data that affect the efficiency of capturing outcomes of interest.[1] The authors used endovascular aneurysm repair (EVAR) devices as a use case to assess methodologic requirements and feasibility of conducting postmarket device safety studies using clinical data.

In this retrospective cohort study, investigators used data from electronic health records from the Veterans Affairs health care system to identify patients who underwent EVAR from January 1, 2011, to December 21, 2021. Devices evaluated were three successive versions of the AFX device (Endologix, Inc.) ("AFX devices") and four non-AFX devices (Endurant [Medtronic], Gore Excluder [Gore & Associates], Zenith [Cook Medical], and Treo [Terumo Aortic]) ("non-AFX devices").

The primary outcome measures were rates of type III endoleaks and all-cause mortality, assessed using Cox proportional hazard regression and doubly robust causal modeling.

All devices are required by FDA to have a UDI, but these have not been integrated into most health care systems. In this cohort, UDIs were only available for a limited number of patients (0% for AFX devices and 0.1% for non-AFX devices). Therefore, natural language processing (NLP) tools were developed using NILE software to identify unstructured text describing the devices of interest and determine the patient cohort for analysis.

In total, 13,941 patients underwent EVAR with a study device (mean age, 71.8 years; 85.1% White); 718 patients were implanted with an AFX device, and 12,137 received a non-AFX device.

KEY FINDINGS

- There was an increased risk of type III endoleaks with AFX devices as compared with non-AFX devices.
- There was no increase in all-cause mortality.
- Few records used UDIs, and relevant structured data were inconsistent, which required the development of custom NLP tools for this analysis.

After the EVAR procedure, 840 (6.0%) patients had a type III endoleak. By 5 years, the risk of experiencing a type III endoleak was significantly higher for patients who received an AFX device as compared with a non-AFX device, including for the most recent iteration of the AFX device, AFX2.

Over the study period, 2,148 (15.4%) patients died. Analysis revealed that there were no significant differences in all-cause mortality between AFX and non-AFX device groups.

Limitations of this study included the possibility that patients treated with the devices of interest were not captured or were misclassified, the inability to distinguish between types of type III endoleak, and limited generalizability of the results to female patients.

This study showed that use of postmarket surveillance data from a large data set to assess device safety is feasible, but challenges of missing and inconsistent data need to be considered, noted the investigators.

1. Wang X, Ayakulangara Panickan V, Cai T, et al. Endovascular aneurysm repair devices as a use case for postmarketing surveillance of medical devices. JAMA Intern Med. Published online August 21, 2023. doi: 10.1001/jamainternmed.2023.3562

ENDOVASCULAR TODAY ASKS…

We asked study investigator Florence T. Bourgeois, MD, MPH, with Harvard Medical School and the Harvard-MIT Center for Regulatory Science, in Boston, Massachusetts, to discuss the study's challenges and how postmarket surveillance data can be used for future research.

As you pulled data for the study, you found that UDIs were only available for a limited number of patients and created custom NLP tools to extract device information from clinical notes. What were the challenges and limitations to using NLP tools versus UDIs? What are the hurdles to more widespread use of UDIs, and how can we overcome them?

Creating NLP classifiers to identify specific devices is a resource-intensive process, as it requires extensive manual chart review to develop and validate these tools. The approach ultimately is not scalable or well-suited to a larger surveillance system, since new classifiers need to be developed for every device of interest. Further, the device-specific information needed to identify devices, including product numbers and device names, is inconsistently recorded in medical records, given the lack of requirements for structured clinical data entry for devices. This creates additional challenges and risks incomplete capture of patients treated with certain devices.

To address this limitation, the FDA issued the UDI rule in 2013, requiring device manufacturers to include a unique device and production identifier for every marketed device. Use of these UDIs in health technology systems would enable easy documentation and tracking of devices and lead to a number of benefits around patient safety. However, the FDA does not have the authority to require UDI integration within health care systems and few have done so voluntarily to date. Given the perceived burdens by health care institutions in implementing UDIs into health care record systems, it is likely that federal regulation would be needed to achieve broad adoption of UDIs.

EVAR devices were chosen as a use case for this analysis because of their widespread use for abdominal aortic aneurysm repair, ongoing safety concerns, and extended surveillance period after implantation. In which other medical device class(es) might an evaluation of postmarket surveillance data be beneficial? What should be considered when using postmarket surveillance data for future analyses?

The FDA posts medical device safety communications on its website. These communications represent safety issues that have been identified for specific devices, with 30 such communications issued in 2022. For some of these devices, the FDA is continuing to monitor postmarket safety, and evaluations using clinical data, as in this study, could be useful in assessing device risks. In designing such studies, it is critical that clinical data be selected that is representative of the general patient population treated with the devices and that there is reliable and consistent documentation of device use, either with UDIs or other device data. ■