Researchers: No added risk of death with drug-coated devices used for lower body procedure

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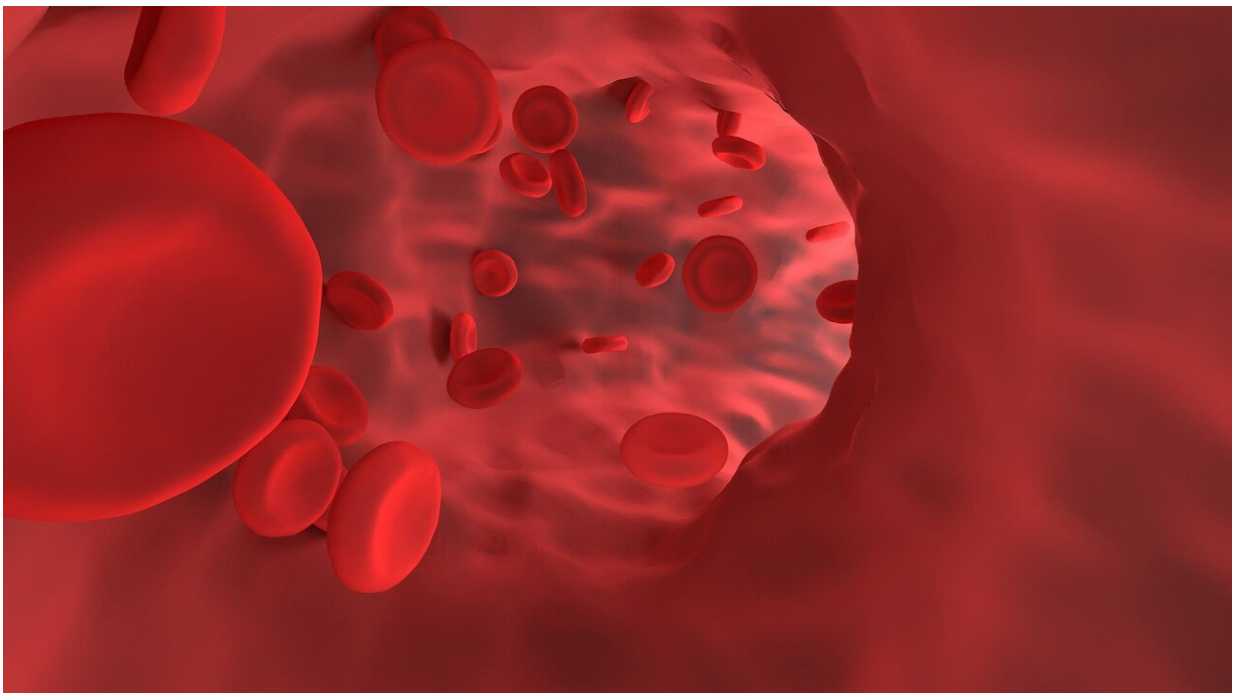

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Peripheral artery disease (PAD), or blockages in the arteries outside of the heart, affects more than 200 million people worldwide and 12.5 million people in the United States. Patients with this circulatory disorder may develop severe leg pain or unhealing wounds that require a

minimally invasive revascularization procedure to open the blood vessels to improve blood flow.

For nearly a decade, proceduralists and surgeons have depended on devices coated with a drug called paclitaxel—which reduces the need for another procedure by up to 50 percent—during procedures to open the arteries of the leg. However, in the wake of a 2018 study that found a potential link between these drug-coated peripheral devices and death after two years post procedure, the FDA restricted the use of these devices for the treatment of PAD out of an abundance of caution.

At the behest of the FDA, cardiologists Eric Secemsky, MD, and Robert Yeh, MD, both of the Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology at Beth Israel Deaconess Medical Center (BIDMC), designed the Safety Assessment of Femoropopliteal Endovascular Treatment With Paclitaxel-coated Devices (SAFE-PAD) study to provide the information necessary to make scientifically-sound regulatory decisions about the safety of these devices. Using claims data from the Centers for Medicare & Medicaid Services (CMS), the researchers evaluated survival following treatment with these drug-coated devices in more than 160,000 leg artery revascularization procedures conducted between 2015 and 2018.

The team found no statistically significant difference in mortality between patients treated with drug-coated devices and non-drug-coated devices. The report was presented as a late-breaking study at the American College of Cardiology's Scientific Sessions May 16 and published simultaneously in *JAMA Internal Medicine*.

"Our study of Medicare beneficiaries includes more than 160,000 patients, including more than 30,000 patients with survival data extending past four years, making it one of the largest and most comprehensive evaluations of the safety of drug-coated devices to be

published since the initial analysis," said Secemsky, Director of Vascular Intervention at BIDMC and Assistant Professor of Medicine at Harvard Medical School. "Although the 2018 findings raised concerns about the safety of these drug-coated devices, there were many issues with that analysis—including the study's small size and a lack of complete patient follow-up."

Secemsky and colleagues' study included Medicare patients treated with either a drug-coated or non-drug coated peripheral device between 2015-2018 at nearly 3000 hospitals across the United States. Deaths were evaluated through May 2020, and after accounting for any differences in demographics and co-morbidities between the two groups, the investigators found no evidence that drug-coated devices were associated with higher mortality rates through an average 2.7 years of follow-up, with some patients having follow-up through 5 years.

"We used a number of novel statistical methods to assure these results were accurate, and found consistent results across a number of different patient groups—including among those of lower overall risk, those with more severe disease, and those treated in outpatient centers," Secemsky said. "We've provided these results to the FDA to make decisions on whether to continue to restrict these drug-coated devices to only those at high risk of needing another leg procedure, or to return to the previous indications where these were used without restriction."

The current publication is the first report of seven planned biannual reports as part of the SAFE-PAD study, which was designed to continue until all patients in the study had follow-up exceeding 5 years. As such, Secemsky and colleagues will continue to analyze these Medicare beneficiaries and update their findings until this study completes in late 2023.

More information: Eric A. Secemsky et al. Longitudinal Assessment

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of Safety of Femoropopliteal Endovascular Treatment With Paclitaxel-Coated Devices Among Medicare Beneficiaries, *JAMA Internal Medicine* (2021). DOI: 10.1001/jamainternmed.2021.2738

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