

Study finds bleeding after minimally invasive pad treatments can increase risk of death

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Major bleeding occurs in about 4 percent of surgical procedures to treat blockages in the arteries of the lower leg and leads to an increased risk of in-hospital deaths, according to a new study published in *JACC: Cardiovascular Interventions*. The study found several risk factors that increase the chance of bleeding, which researchers said can help guide future efforts to reduce bleeding complications. The study is the first published research using NCDR PVI Registry data.

"This is the first large-scale study to describe the frequency of bleeding in [patients](#) undergoing lower extremity peripheral vascular interventions (PVI)," said Adam C. Salisbury, MD, MSc, a cardiologist with St. Luke's Health System in Kansas City, Missouri, and the study's lead author.

"Bleeding has been well studied in coronary artery procedures but not in vascular procedures involving the lower extremities."

Peripheral vascular intervention (PVI) is a minimally invasive outpatient procedure used to treat peripheral artery disease (PAD), which causes plaque buildup in the [arteries](#) leading to the intestines, head, arms and most commonly the legs. PAD affects approximately 8 million Americans.

The goal of PVI is to restore the flow of blood to the lower extremities, eliminating pain, numbness or need for amputation. The procedure involves using a balloon-tipped catheter and/or stents to open blockages from inside the vessel. Over the past two decades, there has been a rapid growth in the use of PVI for the treatment of PAD, but there are limited

data about the safety outcomes of PVI in routine clinical practice, Salisbury said.

The researchers studied patients undergoing PVI at 76 hospitals in the NCDR PVI Registry from 2014 to 2016. Among 18,289 PVI procedures, [major bleeding](#) occurred in 744 (4.1 percent). The in-hospital death rate was higher in patients who experienced bleeding compared with those who did not (6.6 percent vs. 0.3 percent).

The study found patient characteristics associated with bleeding included age, female sex, heart failure and anemia. Patients with resting leg pain or ulcerations due to poor blood flow were also at higher risk. The researchers found certain surgical strategies were associated with bleeding, such as placing the catheter in an artery other than the femoral artery. The use of thrombolytic ("clot-busting") therapy was also associated with an increased risk of bleeding.

"The findings suggest we can use different procedural strategies, such as using different access points for the catheter, alternative blood thinners or different sizes of equipment, to reduce the risk of bleeding," Salisbury said. "We can use the findings to identify factors and create models to predict who is at higher risk of bleeding. In these patients, we need to be especially careful to avoid doing anything that could increase the risk of bleeding."

In an editorial accompanying the study, Douglas E. Drachman, MD, of Massachusetts General Hospital and Beau M. Hawkins, MD, of the University of Oklahoma Health Sciences Center, wrote that the study "demonstrates that bleeding is a common complication of PVI and that bleeding confers significant clinical risk. For clinicians engaged in the care of patients with lower extremity PAD, this represents an opportunity to establish best practices and improve patient outcomes: it is time to stop the bleeding."

More information: *JACC: Cardiovascular Interventions*, [DOI: 10.1016/j.jcin.2019.03.012](https://doi.org/10.1016/j.jcin.2019.03.012)

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