Treating pulmonary embolism: How safe and effective are new devices?

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Pulmonary embolism (PE), a blood clot lodged in one of the pulmonary arteries in the lungs, is the third leading cause of cardiovascular-related death in the United States. While most patients are treated with anticoagulants (commonly known as blood thinners), the use of novel interventional devices that remove or dissolve clots in the lungs has significantly increased in recent years. Yet, there is little data—particularly, as it pertains to the treatment of patients with "intermediate-risk PE"—that suggests these approaches are more safe and effective than the use of anticoagulation alone, according to a new scientific statement from the American Heart Association (AHA) that was led by Penn Medicine.

The statement will be published today in *Circulation* and simultaneously presented by Jay S. Giri, MD, MPH, an assistant professor of Cardiovascular Medicine in the Perelman School of Medicine at the University of Pennsylvania, at the 5th Annual Pulmonary Embolism Symposium in Boston.

"While the emergence of these interventional devices offers a new approach to treat pulmonary embolism, questions exist about when they should be administered and which patients would benefit the most. This statement aims to help stratify the risks associated with these approaches and guide clinical practice," said Giri, who chaired the multi-disciplinary committee, comprised of 12 experts from nine different institutions, that published the research.

Pulmonary embolism, which is most often caused by blood clots that travel to the lungs from deep veins in the legs, affects as many as 900,000 people each year in the United States. Historically, the majority of patients with PE have been treated with blood thinners, which help to prevent new clots from forming but do not eliminate existing clots. However, adverse outcomes in patients with intermediate and high-risk PE—despite the use of anticoagulants—prompted the development of novel therapeutic approaches, including catheter-directed thrombolysis (dispensing "clot-busting" medication via a catheter that is threaded through the groin) and catheter-based embolectomy (removing the clot through a minimally invasive procedure). As of now, the U.S. Food and Drug Administration (FDA) has cleared two devices for the interventional treatment of PE, though many others are in the development pipeline.

Despite the clearances, there is limited evidence supporting the safety of the interventional therapies against more conservative approaches, partly because of the FDA's decision to designate these devices as Class II (moderate risk), authors say. According to the FDA, Class II devices include wheelchairs and some pregnancy tests, while Class III (high risk) devices—those that present a potential unreasonable risk of illness or injury—include recently evaluated cardiovascular devices, such as transcatheter heart valves and drug-coated balloons for peripheral artery disease. Unlike Class III devices, which require premarket approval from the FDA—the highest form of device regulation—prior to device sales and marketing, Class II devices can receive clearance via the 510(k) clearance pathway. As a result, authors argue that high-level evidence demonstrating the safety and effectiveness of the devices, and justifying their use, will not be available before widespread marketing.

In this statement, researchers sought to raise awareness of the novel treatment approaches, advise of the potential benefits and risks of endovascular PE intervention and outline appropriate uses, including

identifying which patients would derive the greatest benefit. While decisions to use interventional therapy are primarily driven by the severity of a patient's condition and their risk of dying, authors note that it should also be influenced by patient-specific risk factors for comorbidities and bleeding. Finally, the team sought to lay out principles for research in the field, including appropriate study designs and patient criteria for needed future clinical trials.

The team concluded that patients who are at the highest risk of dying of PE and lowest risk for bleeding benefit the most from more invasive therapies. Patients considered low-risk should be treated with anticoagulants alone. The team discouraged routine administration of interventional therapies to patients at intermediate risk, with patients in this group necessitating the most careful personalized assessment of risks and benefits of therapy.

"Given the minimal short-term risk and low cost associated with anticoagulation alone, these interventional therapy devices must prove safety and effectiveness compared to anticoagulants in randomized clinical trials," Giri said. "As we move forward, it's critical to design randomized trials that enable us to measure clinically meaningful differences in patient outcomes and quality of life."

Provided by Perelman School of Medicine at the University of Pennsylvania

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