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Research team finds notable decrease in IVC filter usage after FDA advisory

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Deep vein thrombosis (DVT) is a medical condition in which blood clots develop in the deep veins of the body, often in the legs, thigh or pelvis. These clots can break loose and travel to the lungs and can cause a life-threatening condition called pulmonary embolism (PE). An inferior vena cava (IVC) filter is a small, basket-like device made of wire that is inserted into the inferior vena cava, a large vein that returns blood from the lower body to the heart and lungs, to capture the blood clots and prevent them from reaching the lungs. IVC filters are implanted in patients at risk for PE when anticoagulant therapy is ineffective or cannot be used.

While IVC filter usage has increased rapidly over the years, its safety has been questioned. In 2010, the U.S. Food and Drug Administration (FDA) issued a device safety communication after reviewing more than 900 adverse events related to the filters over a five-year period. Those adverse events included device migration, embolizations, perforation of the IVC, and filter fractures. Some of these events led to adverse clinical outcomes in patients, often with the filter remaining in the body long after the risk of PE had subsided. Out of concern that these IVC filters were not always removed once a patient's risk for PE subsided, the FDA safety communication recommended removal of the filter as soon as protection from PE is no longer needed.

A research team led by Riyaz Bashir, MD, FACC, RVT, Professor of Medicine at the Lewis Katz School of Medicine at Temple University (LKSOM), and Director of Vascular and Endovascular Medicine at

Temple University Hospital (TUH), examined nationwide utilization rates of IVC filter placement in the United States and assessed what impact the 2010 FDA advisory had on these rates. The team's findings were published in the July 10 issue of *JAMA Internal Medicine*.

"The findings of this study are noteworthy as they reflect the critical need for publications reflecting safety issues related to medical therapies even after they have been approved by FDA. The significant decrease in IVC filter implantations after the FDA communication reflects that such communications are a very powerful means of affecting contemporary practice patterns around the country," says Dr. Bashir.

"Since venous thromboembolism (VTE) is a diagnosis that includes both DVT and PE, in this study we also evaluated VTE-related hospitalization rates during the same period in order to determine whether any change in IVC filter implantation could be accounted for by changes in VTE-related hospitalizations."

The research team used the National Inpatient Sample (NIS) database to identify all patients in the U.S. that underwent IVC filter implantation from January 2005 to December 2014. The researchers also identified all patients diagnosed with DVT or PE during the study period, as well as the rates of IVC filter implantation, and VTE-related hospitalizations per 100,000 in the U.S. population.

Among the team's findings:

- An estimated 1,131,274 patients underwent IVC filter placement over the 10-year study period
- There was a 22.2% increase in the rate of IVC filter placement from 45.2/100,000 in 2005 to 55.1/100,000 in 2010.
- Following the FDA safety communication, there was a 29% decrease in the rate of IVC filter placement from 55.1/100,000

in 2010 to 39.1/100,000 in 2014.
- The rate of VTE-related hospitalizations remained steady between 2010 and 2014.

Despite the significant reduction in IVC filter use following the FDA advisory, implantation rates across the U.S. remain high compared to the IVC filter implantation rate in five large European countries each of which was less than 3/100,000 population.

"In the United States, the IVC filter implantation rates are 25 fold higher than in Europe. The hospitals across this country collectively are spending close to a billion dollars on these devices every year without a known significant benefit. With current level of evidence we believe that the appropriate implantation rate in the U.S. should be similar to, or lower than, the rate observed in Europe," says Dr. Bashir.

Provided by Temple University