Embolic protection device may prevent some strokes during heart valve operations

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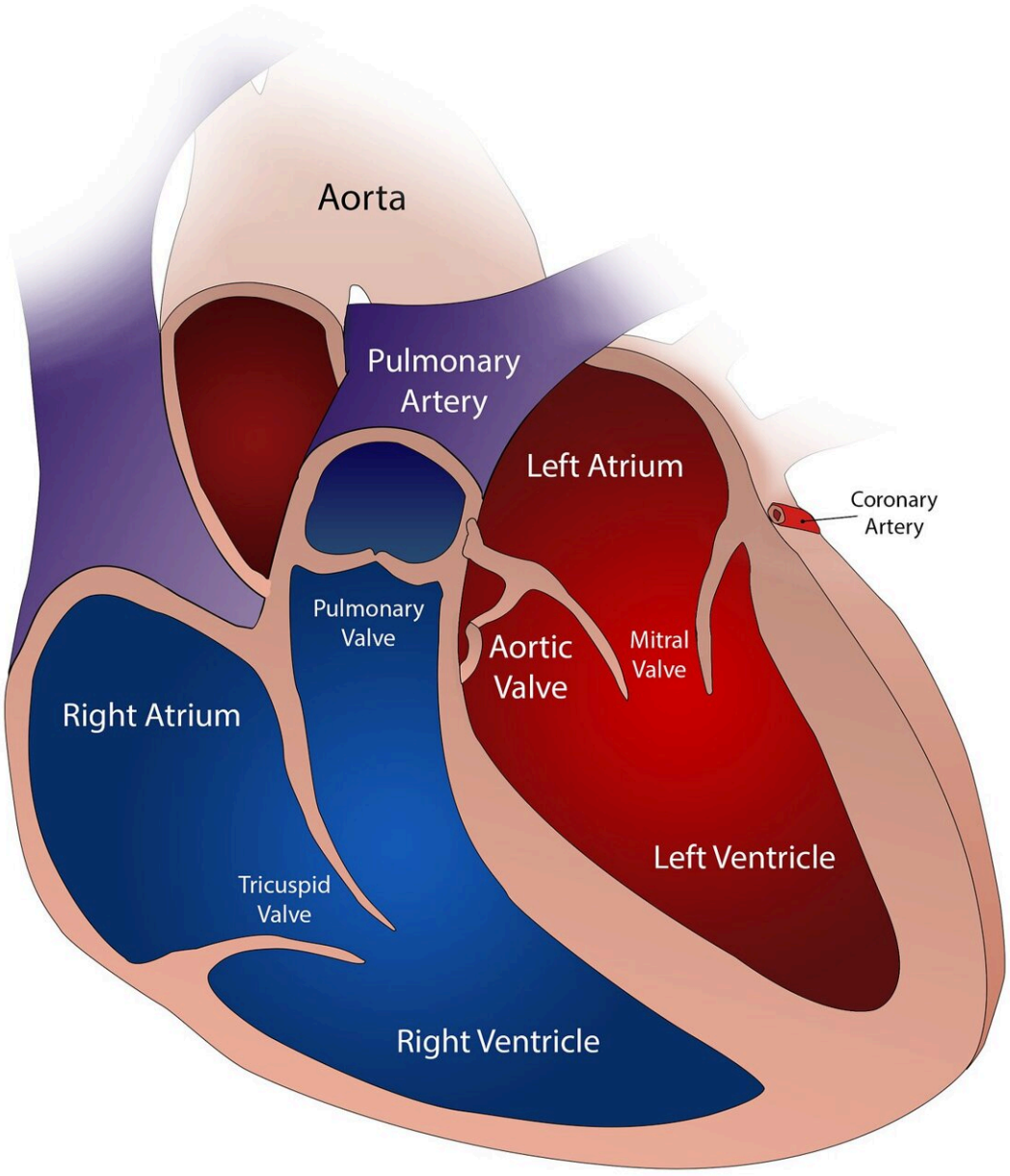

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Recently published research shows that a medical device may be beneficial for patients who have previously had a stroke and are planning to undergo a transcatheter aortic valve replacement, a type of heart valve operation.

Neel Butala, MD, an assistant professor in the Division of Cardiology at the University of Colorado Department of Medicine, is the first author of the article, which was presented as a late-breaking clinical trial at the New York Valves 2024 conference and simultaneously published in *Circulation: Cardiovascular Interventions*.

The study aimed to gather more information on how beneficial a cerebral embolic protection device was at mitigating the risk of a stroke during a transcatheter aortic valve replacement.

"This device had been approved, but we didn't really know if it was useful or not," Butala says. "By using a large dataset, we tried to find answers, and we ultimately found that patients who have had a prior stroke are the most likely to benefit from the device."

What is TAVR?

A transcatheter aortic valve replacement—also referred to as TAVR—is a less invasive procedure for patients with severe aortic stenosis.

"Aortic stenosis is a narrowing of the aortic valve which allows blood to flow out of your heart to your body, and narrowing of this valve causes your heart to work more," Butala says. "The valve does narrow over time as people get older, but some people have severe narrowing. When this happens and a person experiences symptoms, we need to act and replace the valve."

For many years, the traditional way of addressing severe aortic stenosis

was open-heart surgery. However, because many people with severe aortic stenosis are in their 70s and 80s, they are often not good surgical candidates.

"TAVR was developed as a minimally invasive approach. We go in through an artery in the leg and basically put a long, thin tube across the aortic valve. Then, through that tube, we deliver a scrunched up aortic valve," he says. "We can blow up a balloon on the inside of the aortic valve to allow the new transcatheter valve to expand to its normal height, or we can use a self-expanding transcatheter valve.

"This puts a new valve inside of your existing aortic valve, and that allows blood to flow and leave the heart without any narrowing," he adds.

Trying to mitigate the risk of stroke

Nowadays, transcatheter valve replacement has become streamlined and there generally are low risks of complications, Butala explains.

"However, one complication that remains is a stroke. When you expand the new valve inside the existing valve, flecks of calcium can go to the brain, which may lead to blockages of blood vessels in the brain and a stroke," he says. "In roughly 1.5% to 2% of all cases, there is a stroke as a byproduct of the procedure. It's a persistent complication that we haven't really solved yet, and thus far, there have not been good predictors of who gets a stroke."

To address this, a device—called an embolic protection device—was developed to prevent a stroke by putting filters in the blood vessels that go to the brain.

"There is only one device available on the market currently in the U.S.,"

Butala says. "It essentially has little baskets that protect three of the four blood vessels that go to the brain from the heart. The thinking is, if there are chunks of calcium, they will be captured in these baskets that will then be removed and a stroke will be prevented."

Despite the intuitive nature of these devices, the data supporting them was lacking. There have been several studies on whether embolic protection devices reduce stroke during a transcatheter aortic valve replacement, and a lot of them had mixed results.

"Previously, we did a large observational study using a dataset that included all transcatheter aortic valve replacements in the U.S. From our analysis, we found that there was no difference in stroke after the procedure regardless of whether you used the device or not," he says.

In a randomized trial, called the PROTECTED-TAVR trial, data showed the device did not reduce the incidence of strokes happening within 72 hours of the procedure. However, the data suggested the device did lead to a 62% reduction in "disabling stroke," meaning a stroke that is of greater severity and leads to more disabling symptoms.

"With the mixed results, there was still controversy as to the utility of this device. The medical field was still confused—should we use this device or not?" Butala says.

Investigating whether the device reduces disabling stroke

Given the mixed results of the PROTECTED-TAVR trial, Butala's research article focused on the efficacy of the device in reducing disabling stroke.

The investigators decided to use discharge location information from a data registry as a marker of how severe a patient's stroke was.

"The thinking is, if you get discharged from the hospital and go to a care facility, such as a nursing home or rehabilitation facility, then your stroke was probably more disabling than if you were discharged home," he says. "Ultimately, we developed a novel method for identifying a disabling stroke."

The study population consisted of 414,649 patients. Of those, 53,398 patients received an embolic protection device. This is the largest study to date among patients undergoing a transcatheter aortic valve replacement.

Overall, the data showed the use of the device was associated with a small, borderline significant reduction in disabling stroke—a much smaller reduction than what the PROTECTED-TAVR trial found, Butala explains. The device was not associated with a reduction in non-disabling stroke.

"A theory for why there was not a reduction in non-disabling stroke is that there may be tiny calcium particles that are able to float by the baskets, or maybe the baskets themselves, as they are placed in the body, can damage the blood vessels and cause a tiny stroke," he says.

The investigators also found that the benefit of the device was greater among those who had previously had a stroke compared to those who had never had a stroke before.

"The data shows that for this subgroup of people with a prior stroke, there was a significant benefit of a decent magnitude. This is the first time anyone has ever found a subgroup that would benefit from this device," he says. "A potential recommendation may be that this device

should be used more routinely for patients who have had a prior stroke. For other patients, it's unclear if the device will benefit them.

"I don't think it's going to cause harm, but there is a cost to the device in terms of time and money," he adds.

Looking ahead, Butala hopes to see more innovators developing devices that can do an even better job at protecting patients.

"There's obviously a need for innovation here to really find something that can protect against stroke for patients undergoing a transcatheter aortic valve replacement, because this procedure is becoming more and more popular, even among younger patients," he says.

"The overall efficacy of this device is still an unsolved problem," he adds. "We added more information through our findings that the device can reduce disabling stroke in some patients, although the magnitude is small. But as these devices are being used on even younger patients, we need to get a better sense of what we can do to prevent strokes."

More information: Neel M. Butala et al, Impact of Cerebral Embolic Protection Devices on Disabling Stroke after Transcatheter Aortic Valve Replacement: Updated Results from the STS/ACC TVT Registry, *Circulation: Cardiovascular Interventions* (2024). DOI: 10.1161/CIRCINTERVENTIONS.123.013697

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