

# Yale leads test of new device that protects the brain during heart-valve procedure

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In the first multicenter trial of its kind, Yale researchers tested a new device that lowers the risk of stroke and cognitive decline in patients undergoing heart-valve replacement.



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The preliminary findings of the DEFLECT III trial were presented by Dr. Alexandra Lansky, associate professor of medicine (cardiology) at Yale School of Medicine, on March 15 at the American College of Cardiology's 64th Annual Scientific Session in San Diego, CA.

Stroke is a devastating complication of transcatheter aortic valve replacement (TAVR), a minimally invasive procedure to repair a damaged heart valve without surgery. Up to 7% of TAVR patients suffer strokes due to the release of emboli, or particulate material such as a plaque, that travel in the blood from the heart to the brain during the valve procedure.

Led by co-principal investigators Lansky and Dr. Andreas Baumbach, of Bristol Heart Institute, the research team conducted a preliminary trial of the TriGuard, a device that is placed in the aortic arch during TAVR. The device has a mesh filter that covers the three major cerebral blood vessels, preventing the release of emboli from the aorta to the brain.

Conducted in centers in Europe and Israel, the exploratory trial enrolled 83 subjects and randomized them for TAVR with and without TriGuard protection. In patients with protection, the researchers observed fewer ischemic brain lesions and lesions of reduced volume.

"One of the major findings is, for the first time, we're showing that with protection, 55% more patients have completely clean brains - with no ischemic brain lesions at all," said Lansky. Brain lesions increase risk of dementia and stroke two- to three-

fold.

"What's more exciting are the neurocognitive findings," noted Lansky. The researchers used the Montreal Cognitive Assessment (MoCA) to evaluate the impact of TriGuard on cognitive factors such as language, memory, attention, recall, and orientation. "Whether we're looking at MoCA or looking at short-term memory or delayed memory, we're seeing an improvement in cognitive function as early as hospital discharge among protected patients, compared to controls," she explained.

These preliminary findings provide the basis to design a conclusive randomized clinical trial. "DEFLECT III is helping us design the next study, which will be definitive," Lansky noted.

Other authors include Joachim Schofer, Szilard Voros, Adam Brickman, Thomas Cuisset, Didier Tchetché, Pieter Stella, Daniel Blackman, Michael Cleman, John Forrest, Joseph Brennan, Abeel Mangi, Gil Bolotin, Jochen Reinöhl, Stefan Spitzer, Martine Gilard, David Hildick-Smith, Michael Haude, and Andreas Baumbach

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