

Device reduces risk of brain injury after heart valve replacement

August 9 2016

Among patients with severe aortic stenosis (narrowing of the aortic valve) undergoing transcatheter aortic valve implantation, the use of a cerebral protection device (a filter that captures debris [tissue and plaque] dislodged during the procedure) reduced the number and volume of brain lesions, according to a study appearing in the August 9 issue of *JAMA*.

Although the [clinical outcomes](#) of transcatheter [aortic valve](#) implantation (TAVI; replacement of the aortic valve, delivered via a blood vessel with a catheter) have improved considerably during the last decade, stroke, which is associated with a 3-fold increase in mortality following TAVI, remains an important concern. Adding to this concern is the observation that ischemic lesions are found in as many as 80 percent of TAVI patients. Numerous devices have been developed to protect the brain from injury caused by embolic debris during TAVI, although clear evidence of the efficacy of any embolic protection device in TAVI is still missing.

Axel Linke, M.D., of the University of Leipzig, Germany, and colleagues randomly assigned 100 higher-risk patients with [severe aortic stenosis](#) to undergo TAVI with a [cerebral protection](#) device (n = 50; filter group) or without a cerebral protection device (n = 50; [control group](#)). Brain magnetic resonance imaging (MRI) was performed at study entry, 2 days, and 7 days after TAVI.

The researchers found that the number of new [brain lesions](#) 2 days after

TAVI was lower in the filter group (4) than in the control group (10). New lesion volume after TAVI was lower in the filter group (242 mm³) vs in the control group (527 mm³).

Regarding adverse events, 1 patient in the control group died prior to the 30-day visit. Life-threatening hemorrhages occurred in 1 patient in the filter group and 1 in the control group. Major vascular complications occurred in 5 patients in the filter group and 6 patients in the control group. One patient in the filter group and 5 in the control group had acute kidney injury, and 3 patients in the filter group had a thoracotomy (surgical incision into the chest wall).

"Larger studies are needed to assess the effect of cerebral protection device use on neurological and cognitive function after TAVI and to devise methods that will provide more complete coverage of the brain to prevent new lesions," the authors write.

([DOI: 10.1001/jama.2016.10302](https://doi.org/10.1001/jama.2016.10302); the study is available pre-embargo to the media at the For the Media website)

Editor's Note: The Leipzig Heart Center received a grant from Claret Medical and Medtronic. Please see the article for additional information, including other authors, author contributions and affiliations, financial disclosures, etc.

Editorial: Improving Outcomes From Transcatheter Aortic Valve Implantation

The results from this trial demonstrates 2 important points, write Steven R. Messe, M.D., of the University of Pennsylvania, Philadelphia, and Michael J. Mack, M.D., of the Heart Hospital Baylor Plano, Plano, Texas, in an accompanying editorial.

"First, as other studies have noted, emboli to the brain that cause infarction detected on MRI are very common with TAVI. In this trial, acute lesions on MRI were present in virtually all patients enrolled, although the vast majority of these lesions were quite small. Second, use of an embolic protection device can successfully reduce cerebral infarct number and volume. Whether that reduction translates to a meaningful improvement in clinical outcomes will require more study, but the findings represent a compelling and encouraging start."

More information: *JAMA*(2016). [DOI: 10.1001/jama.2016.10316](https://doi.org/10.1001/jama.2016.10316)

Provided by The JAMA Network Journals

Citation: Device reduces risk of brain injury after heart valve replacement (2016, August 9)
retrieved 4 May 2024 from
<https://medicalxpress.com/news/2016-08-device-brain-injury-heart-valve.html>

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