

# Results from the SENTINEL trial presented

November 1 2016

---

A multicenter randomized trial evaluating the role of embolic protection using the Sentinel device during transcatheter aortic valve replacement (TAVR) found that the device was safe but did not meet the primary efficacy endpoint of reduction in median new lesion volume in protected territories assessed by MRI at 2-7 days. In addition, neurocognitive function was not significantly improved.

Findings from the SENTINEL trial were reported today at the 28th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine. The study was also simultaneously published in The Journal of the American College of Cardiology (JACC).

TAVR is an important therapy for high and intermediate-risk patients with [severe aortic stenosis](#) (AS). However, strokes remain a concerning complication after TAVR and are associated with increased mortality and morbidity. The Sentinel transcatheter cerebral embolic protection (TCEP) device consists of two filters within a single six French delivery catheter percutaneously placed from the right radial (preferred) or brachial artery over a 0.014" guide wire. The filters are positioned in the brachiocephalic and the left common carotid arteries before TAVR and are withdrawn into the catheter and removed after TAVR. The SENTINEL trial was designed to assess the safety of the device during TAVR and the efficacy in reducing the effects of cerebral embolization.

The prospective multicenter randomized trial included 363 patients with severe symptomatic AS and planned TAVR who were at high risk for surgery at 17 centers in the U.S. and two centers in Germany. Patients were randomized 1:1:1 into a safety arm (TCEP only) and two imaging cohorts, in which patients were randomly assigned to TAVR with TCEP (device arm) or without TCEP (control arm). Blinded diffusion weighted MRI (DW-MRI) and neurocognitive function assessments were performed in the device and control arms. Particulate debris from the extracted filters was studied in the device arm and all patients underwent rigorous neurologic evaluations post-TAVR, at 30 days and at 90 days. The

primary safety end point was the occurrence of major adverse cardiac and cerebrovascular events (MACCE) at 30 days compared to a historical performance goal.

The study found MACCE (7.3%) in the device and safety arms was non-inferior to the performance goal (18.3%, Pnoninferior

Citation: Results from the SENTINEL trial presented (2016, November 1) retrieved 10 May 2024 from <https://medicalxpress.com/news/2016-11-results-sentinel-trial.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--