



Results Demonstrating Favorable Outcomes with TCAR vs. TF-CAS in Patients with Carotid Artery Stenosis Published in the Journal of the American Medical Association (JAMA)

December 17, 2019

SUNNYVALE, Calif., Dec. 17, 2019 (GLOBE NEWSWIRE) -- [Silk Road Medical, Inc.](#) (Nasdaq: SILK), a company focused on reducing the risk of stroke and its devastating impact, today announced that positive results from the ongoing [TransCarotid Artery Revascularization \(TCAR\) Surveillance Project](#) comparing TCAR and transfemoral carotid artery stenting (TF-CAS) have been published in [The Journal of the American Medical Association \(JAMA\)](#)¹.

"These results showed a significantly lower risk of stroke or death for TCAR versus TF-CAS and further contribute to the groundswell of clinical evidence showing the benefits of TCAR," said Dr. Schermerhorn of Beth Israel Deaconess Medical Center. "I am confident that the growing evidence base coupled with publication of these data in JAMA, a peer-reviewed journal, will incrementally drive TCAR towards standard of care."

The study evaluated patients who underwent carotid procedures between 2016 and 2019, with 5,251 patients receiving TCAR compared to 6,640 patients receiving TF-CAS, with 3,286 patients in each group analyzed using propensity score matching. TCAR was associated with significantly lower rates of in-hospital stroke or death (TCAR, 1.6%; TF-CAS, 3.1%, $p<0.001$) as well as the individual rates of stroke (TCAR, 1.3%; TF-CAS, 2.4%, $p=0.001$) and death (TCAR, 0.4%; TF-CAS, 1.0%, $p=0.008$). Additionally, there were no statistical differences noted between TCAR and TF-CAS for in-hospital myocardial infarction (TCAR, 0.2%; TF-CAS, 0.3%, $p=0.47$).

TCAR procedures were also associated with less radiation (median fluoroscopy time, TCAR 5 min; TF-CAS 16 min; $p<0.001$) and contrast use (TCAR, 30 mL; TF-CAS, 80 mL, $p<0.001$). Further, patients who underwent TCAR were significantly less likely to fail the CMS-recommended discharge criteria (TCAR, 16.4%; TF-CAS, 22.7%, $p<0.001$), including length of stay greater than 2 days (TCAR, 13.9%; TF-CAS, 19.0%, $p<0.001$) and failed discharge home (TCAR, 7.3%; TF-CAS, 12.7%, $p<0.001$).

In a separate risk adjusted analysis looking at patients with one year follow up, ipsilateral stroke or death at one year was lower in TCAR vs TF-CAS (TCAR, 5.1%; TF-CAS, 9.6%, $p<0.001$).

"These results continue to prove TCAR's superiority to competitive treatment options, while highlighting the remarkable consistency and reproducibility of these data," said Erica Rogers, Chief Executive Officer. "This milestone publication validates the effectiveness of TCAR as a treatment option for patients with carotid artery disease, while further broadening physician awareness, which we believe will ultimately drive increased confidence and adoption."

The TCAR Surveillance Project, a key initiative of the Society for Vascular Surgery's [Vascular Quality Initiative \(VQI\)](#), is an open-ended registry intended to compare real-world patient outcomes between TCAR and other alternatives.

About TCAR with the ENROUTE Transcarotid Neuroprotection and Stent System

TCAR (TransCarotid Artery Revascularization) is a clinically proven procedure combining surgical principles of neuroprotection with minimally invasive endovascular techniques to treat blockages in the carotid artery at risk of causing a stroke. The ENROUTE Transcarotid Stent is intended to be used in conjunction with the ENROUTE Transcarotid Neuroprotection System (NPS) during the TCAR procedure. The ENROUTE Transcarotid NPS is a first in class device used to directly access the common carotid artery and initiate high rate temporary blood flow reversal to protect the brain from stroke while delivering and implanting the ENROUTE Transcarotid Stent.

About Silk Road Medical

Silk Road Medical, Inc. is a medical device company located in Sunnyvale, California, that is focused on reducing the risk of stroke and its devastating impact. The company has pioneered a new approach for the treatment of carotid artery disease called TransCarotid Artery Revascularization (TCAR). TCAR is a clinically proven procedure combining surgical principles of neuroprotection with minimally invasive endovascular techniques to treat blockages in the carotid artery at risk of causing a stroke.

ENROUTE is a registered trademark of Silk Road Medical, Inc.

INVESTOR CONTACT

Lynn Lewis
investors@silkroadmed.com

MEDIA CONTACT

Joni Ramirez
Merryman Communications
joni@merrymancommunications.com
323-532-0746

¹ Marc L. Schermerhorn, MD, Patric Liang, MD, Jens Eldrup-Jorgensen, MD, *et al.* Revascularization vs Transfemoral Carotid Artery Stenting with Stroke or Death among Patients with Carotid Artery Stenosis. *The Journal of the American Medical Association*. 2019; 322(23):2313-2322. DOI: 10.1001/jama.2019.18441



Source: Silk Road Medical