

Compelling Outcomes with TCAR vs. CEA in Patients with Carotid Artery Stenosis Published in the Annals of Surgery

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SUNNYVALE, Calif., Sept. 21, 2020 (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 <u>TransCarotid Artery Revascularization (TCAR) Surveillance Project</u> comparing TCAR and carotid endarterectomy (CEA) have been published in <u>Annals of Surgery</u>¹.

"These results continue to show low in-hospital stroke, death, and combined stroke/death rates as well as statistically lower rates of in-hospital cranial nerve injury and in-hospital myocardial infarction compared to CEA," said Dr. Mahmoud Malas, Chief of Vascular and Endovascular surgery at UC San Diego Health. "These promising outcomes will likely increase the role of TCAR in the management of carotid artery stenosis."

The study evaluated patients who underwent carotid procedures between 2016 and 2019, with 6,384 patients in each group analyzed using propensity score matching. TCAR was associated with significantly lower rates of in-hospital myocardial infarction (TCAR, 0.5%; CEA, 0.9%, p=0.005) as well as cranial nerve injury (TCAR, 0.4%; CEA, 2.7%, p<0.001). Additionally, there were no statistical differences noted between TCAR and CEA for in-hospital stroke/death (TCAR, 1.6%; CEA, 1.6%, p=0.945) as well as stroke (TCAR, 1.4%; CEA, 1.4%, p=0.881) and death (TCAR, 0.4%; CEA, 0.3%, p=0.662). Patients receiving TCAR procedures were also less likely to stay in the hospital for more than one day (TCAR, 26.4%; CEA, 30.1%, p<0.001). At one year, the incidence of ipsilateral stroke or death was similar between the two groups [HR (95%CI):1.09(0.87–1.36), P=0.44].

"The publication of these data in the *Annals of Surgery* further validates the effectiveness of TCAR as a treatment option for patients with carotid artery disease, while highlighting the consistency of these data," said Erica Rogers, Chief Executive Officer. "We are confident that the updated results from the TCAR Surveillance Project, taken together with the recent publication of ROADSTER 2 data in *Stroke*, will continue to drive adoption of TCAR towards the standard of care."

The TCAR Surveillance Project, a key initiative of the Society for Vascular Surgery's <u>Vascular Quality Initiative (VQI)</u>, 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. (NASDAQ: SILK), 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. For more information on how Silk Road Medical is delivering brighter patient outcomes through brighter clinical thinking, visit www.silkroadmed.com and connect on Twitter, LinkedIn and Facebook.

Investors:

Lynn Lewis or Caroline Paul Gilmartin Group investors@silkroadmed.com

Media:

Michael Fanucchi Silk Road Medical mfanucchi@silkroadmed.com

¹ Mahmoud B. Malas MD, MHS; Hanaa Dakour-Aridi MD; Vikram S. Kashyap MD, *et al.* TransCarotid Revascularization with Dynamic Flow reversal versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. *Annals of Surgery.* September 15, 2020; 322(23):2313-2322. DOI: 10.1097/SLA.00000000000004496



Source: Silk Road Medical