TCAR - Proposal for Physician Credentialing Within Hospital

Overview:
This document is intended to provide talking points and suggestions on how one might establish a TCAR credentialing program within a hospital.

Procedural Summary:
The TCAR® system enables a procedure that combines surgical principles of neuroprotection with minimally invasive endovascular techniques to treat blockages in the carotid artery at risk of causing a stroke. During a TCAR procedure, the ENROUTE® Transcarotid Neuroprotection System is used to directly access the common carotid artery and initiate a high rate of temporary blood flow reversal to protect the brain from stroke while delivering and implanting the ENROUTE® Transcarotid Stent.

The TCAR procedure combines surgical techniques to expose the common carotid artery with endovascular techniques to establish flow reversal and safely deploy the carotid stent implant.

Procedural Detail:
A small, surgical incision is made just above the collar bone to expose the common carotid artery. A soft, flexible sheath is placed directly into the carotid artery and connected to a system that will temporarily reverse flow of blood away from the brain to protect against fragments of plaque that may come loose during the carotid intervention. The blood is filtered then returned through a second sheath placed in the femoral vein in the patient's thigh. After the common carotid artery is surgically clamped proximal to the arterial sheath entry point, the ENROUTE® Transcarotid Neuroprotection System initiates active flow reversal and allows balloon angioplasty and stenting to be performed under fluoroscopy. After the stent is placed to stabilize the plaque in the carotid artery, flow reversal is turned off by unclamping the common carotid artery and blood flow to the brain resumes in its normal direction. The venous sheath is removed and manual compression is used to obtain hemostasis. The arterial sheath is then removed and the artery and incision are surgically closed. Typical flow reversal times are 5-10 minutes.

Data Supporting TCAR:

Study/Data	***Surgical Risk***	***Stroke Rate***
ROADSTER[1]	**High**	• 0.7% - Per protocol (PP) patient population • 1.4% - Intention to Treat (ITT) patient population
ROADSTER 2[2]	**High**	• 0.6% - Per protocol (PP) patient population • 1.9% - Intention to Treat (ITT) patient population
VQI-TSP data	**Standard**	• 1.4%
CREST[3] Study	**Standard**	• 2.3% - CEA • 4.1% - TF-CAS
SVS Registry[4]	**High**	• 3.6% - CEA • 4.9% - TF-CAS

Sources:

[1]Kwolek CJ, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. *J Vasc Surg*. 2015 Nov;62(5):1227-34.

[2]Kashyap VS, et al. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020 Sep;51(9):2620-2629.

[2]Liang P, et al. Expansion of Transcarotid Artery Revascularization to Standard Risk Patients for Treatment of Carotid Artery Stenosis. Oral presentation at the Vascular Annual Meeting; August, 2021; San Diego, CA.

[3]N Engl J Med. 2010 Jul 1;363(1):11-23

[4] J Vasc Surg 2013;57:1318-24 - The impact of Centers for Medicare and Medicaid Services high-risk criteria on outcome after carotid endarterectomy and carotid artery stenting in the SVS Vascular Registry - Marc L. Schermerhorn, MD et al

Proposed Hospital Credentialing Requirements Specific to TCAR:

A starting point for discussion within the hospital, the below are suggested requirements necessary for establishing a TCAR program. Physicians would be able to execute TCAR procedures if they have achieved the following requirements:

1. Open Surgery Privileges:
    a. 25 cerebrovascular, 45 peripheral and 10 complex vascular reconstructions[4]
    [4] J Vasc Surg 2018;67:1337-44.
2. Endovascular Privileges:
    a. 80 endovascular therapeutic procedures and 100 endovascular diagnostic procedures[4]
    [4] J Vasc Surg 2018;67:1337-44.
3. Completion of didactic training course provided by Silk Road Medical covering the surgical and endovascular requirements of the TCAR Procedure:
    a. The course is to include patient selection through film review, medical management pre-procedure, surgical exposure, arterial access, establishing flow reversal, endovascular device delivery, stent system prep/usage training, stent implantation and post-procedure patient care
4. Engage in a 2 hour (minimum) didactic presentation, provided by Silk Road Medical and participate in **one** of the following hands-on programs:
    a. Simulation Course: Trainees to practice using the TCAR® system with cadaver and/or simulation models under the course direction of an experienced TCAR physician
    or
    b. Proctor Program Physicians must complete a minimum of 3 cases under the observation/guidance of a Silk Road Medical designated physician proctor. After completion and acceptable evaluations from physician proctors, the physician will be certified
5. Carotid Stenting Experience for TCAR Credentialing
    a. 10 carotid angiograms with trainee as primary operator on ½
    b. 5 carotid stenting procedures with trainee as primary operator on ½

The Society for Vascular Surgery constituted a task force to provide informed recommendations on the knowledge, technical skills, resources, and infrastructure required to obtain and to maintain privileges for the safe and effective performance of transcarotid artery revascularization (TCAR). You can find those recommendations here: https://www.jvascsurg.org/article/S0741-5214(20)31312-4/fulltext

ENROUTE® Transcarotid Stent System Prescribing Information

Indications for Use

The ENROUTE® Transcarotid Stent System used in conjunction with the ENROUTE® Transcarotid Neuroprotection System (NPS) is indicated for the treatmentof patients at high risk and standard risk for adverse events from carotid endarterectomy, who require carotid revascularization and meet the criteria outlined below.

	High Risk	Standard Risk
With neurological symptoms	≥ 50% stenosis of the common or internal carotid artery by ultrasound or angiogram	≥ 70% stenosis of the common or internal carotid artery by ultrasound or ≥ 50% stenosis of the common or internal carotid artery by angiogram
Without neurological symptoms	≥ 80% stenosis of the common or internal carotid artery by ultrasound or angiogram	≥ 70% stenosis of the common or internal carotid artery by ultrasound or ≥ 60% stenosis of the common or internal carotid artery by angiogram
Reference vessel diameter	Must be within 4.0 mm – 9.0 mm at the target lesion	
Carotid bifurcation location	Minimum 5 cm above the clavicle to allow for placement of the ENROUTE Transcarotid NPS	

Contraindications

Use of the ENROUTE® Transcarotid Stent System is contraindicated in the following patients:
1. Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
2. Patients in whom the ENROUTE® Transcarotid NPS is unable to be placed.
3. Patients with uncorrected bleeding disorders.
4. Patients with known allergies to nitinol.
5. Lesions in the ostium of the common carotid artery.

Warnings

General Warnings

1. Only physicians who have received appropriate training for transcarotid stenting and who are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.
2. The safety and efficacy of the ENROUTE® Transcarotid Stent System have not been demonstrated with embolic protection systems other than the ENROUTE® Transcarotid NPS. Use the ENROUTE® Transcarotid Stent System only with the ENROUTE® Transcarotid NPS.
3. The long term performance (> 3 years) of carotid stents has not yet been established.
4. As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture.
5. The stent may cause a thrombus, distal embolization or may migrate from the site of implant through the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration (see Section 9.3 of these instructions). In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
6. Overstretching of the artery may result in rupture and life-threatening bleeding.
7. In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents (e.g. aspirin) may be adversely affected.
8. The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in Section 9.1 of these instructions.
9. In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.

Non-clinical testing has demonstrated that the ENROUTE® Transcarotid Stent is MR Conditional. A patient with this device can be scanned safely in an MR system meeting the following conditions:
- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000 Gauss/cm (40 Tesla/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode).

Under the scan conditions defined above, the ENROUTE® Transcarotid Stent is expected to produce a maximum temperature rise of 2.4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the ENROUTE® Transcarotid Stent when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system. The artifact does obscure the device lumen.

Potential Adverse Events

Adverse Events (in alphabetical order) that may be associated with the use of the ENROUTE® Transcarotid Stent System when used in conjunction with the ENROUTE® Transcarotid NPS include, but may not be limited to (based upon clinical trial data for the PRECISE Stent System and the ANGIOGUARD XP Emboli Capture Guidewire and clinical trial data from the ROADSTER and PROOF studies):
Air embolism, Allergic/anaphylactoid reaction, Anemia, Aneurysm, Angina/coronary ischemia, Arrhythmia (including bradycardia, possibly requiring need for a temporary or permanent pacemaker), Arterial dissection, Arterial occlusion/restenosis of the treated vessel, Arterial occlusion/thrombus, at puncture site, Arterial occlusion/thrombus, remote from puncture site, Arteriovenous fistula, Atelectasis, Atrial Fibrillation, Bacteremia or septicemia, Cerebral edema, Congestive heart failure, Death, Embolization, arterial, Embolization, stent, Emergent repeat hospital intervention, Fever, Gastrointestinal disorders, GI bleeding from anticoagulation/antiplatelet medication, Hallucination, Hematoma bleed, access site, Hematoma bleed, remote site, Hemorrhage, Hyperperfusion syndrome, Hypotension/hypertension, Hypomagnesaemia, Hypophosphatemia, Infection, Intimal injury/dissection, Ischemia/infarction of tissue/organ, Local infection and pain at insertion site, Malposition (failure to deliver the stent to the intended site), Myocardial infarction, Nausea, Oxygen saturation decrease, Pain, Pseudoaneurysm, Rales, Renal failure, Respiratory Infection, Restenosis of the vessel (> 50% obstruction), Rhinorrhea, Seizure, Severe unilateral headache, Stent migration, Stent thrombosis, Stroke, Transient ischemic attack, Transient intolerance to reverse flow, Urinary tract infection, Vasospasm, Venous occlusion/thrombosis, at puncture site, Venous occlusion/thrombosis, remote from puncture site, Vessel rupture, dissection, perforation, Vomiting, Wheezing

Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
Please refer to package insert for indications, contraindications, warnings, precautions, and instructions for use
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