Technical Tips for Safe, Effective TCAR with the ENROUTE System (Silk Road Medical): When is the Procedure Contraindicated

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Addressing an Unmet Clinical Need

Trans-Femoral Carotid Artery Stenting (TF-CAS)
15 years on Market

Carotid Endarterectomy (CEA)
65 years: Gold standard

HIGH (2x) peri-procedural stroke risk
CREST 30-day All Stroke\(^1\): 2.3% CEA vs 4.1% TF CAS

Low stroke rates & Higher surgical morbidity
CREST CNI\(^2\): 2.1% CNI unresolved at 6 months (80% motor)
CREST MI\(^1\): 2.3% CEA vs 1.1% TF CAS

ROADSTER 1: Results on Par with CEA

30-Day Outcomes

High Surgical Risk
- ROADSTER Pivotal
- ROADSTER Continued Access
- ROADSTER Combined

Standard Surgical Risk
- CREST CEA
- CREST CAS

Bar chart showing comparison of stroke and stroke and death outcomes for different procedures.
Technical aspects of transcarotid artery revascularization using the ENROUTE transcarotid neuroprotection and stent system

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Transcarotid artery revascularization (TCAR) with the ENROUTE transcarotid neuroprotection and stent system (Silk Road Medical, Inc, Sunnyvale, Calif) combines surgical principles of neuroprotection with less invasive endovascular techniques to treat high grade stenosis in the carotid artery. The ENROUTE Neuroprotection System allows the surgeon to directly access the common carotid artery to initiate high rate temporary blood flow reversal to protect the brain while performing carotid angioplasty and stenting. Unprotected catheterization of the arch and lesion is, thus, avoided. Pivotal data from the Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure (ROADSTER) study of high-risk patients undergoing TCAR have showed a low stroke rate compared with other prospective trials of endovascular carotid intervention. The aim of this article is to provide specific technical details of TCAR. (J Vasc Surg 2017;65:916-20.)
TCAR Indications and Contraindications: Focus on Safe Access

Instructions for Use

**ENROUTE® Transcarotid Neuroprotection System (NPS)**

**Indications for Use**

The ENROUTE Transcarotid Neuroprotection System (ENROUTE Transcarotid NPS) is intended to provide transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have appropriate anatomy described below:

- Adequate femoral venous access
- Common carotid artery reference diameter of at least 6 mm
- Carotid bifurcation is a minimum of 5 cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomography (CT) angiography or magnetic resonance (MR) angiography.

**Contraindications**

The ENROUTE Transcarotid NPS is contraindicated for use in patients exhibiting the following conditions:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated
- Patients with unresolved bleeding disorders
- Patients with severe disease of the ipsilateral common carotid artery
- Uncontrollable intolerance to flow reversal (i.e., pre-conditioning does not result in in tolerance to vessel occlusion/flow reversal)
Pre-Procedure Medications

**Dual antiplatelet therapy**

**Aspirin**
- **Optimal:** 75-325 mg / day at least 7 days pre procedure
  
  **OR**

- Loading dose: A 650 mg loading dose of aspirin, provided that it is not enteric coated or extended release, at least 4 hours prior to procedure

**Plavix (Clopidigrel)**
- **Optimal:** 75mg/day for at least 7 days
  
  **OR**

- Loading dose: A 450 mg Plavix loading dose at least 4 hours prior to procedure

**Statin Therapy**

**Lipitor (Atorvastatin)**
- **Optimal:** Lipitor 40mg/day for at least 7 days
  
  **OR**

- Loading Dose: 80mg Atorvastatin at least 12 hours prior to procedure

As described in the 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease: Executive Summary
Procedural Blood Pressure / Heart Rate

Foundation of ENROUTE Neuroprotection System’s reverse flow mechanism is the delta between arterial and venous blood pressure

*Periods of hypotension and bradycardia must be avoided*

**Blood Pressure**

- **140-160mmHg Systolic = Recommended Procedural Pressure Range**
- **Critical that blood pressure is continuously monitored** and stable during the procedure
  - Vasopressors / antihypotensive agents should be available and may be required to manage patient blood pressure greater than 140 mmHg systolic during flow reversal (140-160 target).

**Heart Rate**

- **>70 bpm = Target Procedural Heart Rate**
  - Prophylactic use of atropine or glycopyrrolate is recommended in all patients unless unnecessary (prior CEA or pacemaker) or hazardous (history of severe cad with tachyarrhythmia)
CCA Exposure

1. Patient is placed in supine position
2. Head positioned similar to CEA
3. Incision is made between the heads of the sternocleidomastoid muscle proximal to the omohyoid muscle
4. Longitudinal division of carotid sheath with jugular vein partially dissected and retracted medially
5. A 3-4cm segment of the proximal CCA is dissected circumferentially followed by vessel loop to control the CCA
6. Pre-place the closing suture in the adventitia of the CCA to provide landmark for arteriotomy and to facilitate closure
CCA Access

1. Retraction of the umbilical tape will help immobilize the artery
   • Careful attention must be paid to the **change in vessel shape**

2. CCA stability critical for this step
   • Use shallow angle to promote atraumatic wire & sheath insertion
   • Puncture in-line and central to arterial lumen

- Invagination – dull needle
- Artery ovalized by vessel loop
# Wire Techniques for Arterial Sheath Insertion

**More Wire = More Support**

<table>
<thead>
<tr>
<th>ENGAGE EC VS. STOP SHORT</th>
<th>Recommend Engage EC</th>
<th>Recommend Stop Short</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCA is &gt;7cm</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>CCA is 5-7cm &amp; proximal EC is clear</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>CCA is 5-7cm &amp; proximal EC &lt;50% stenosis without significant angulation at EC origin</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>CCA is 5-7cm &amp; proximal EC is &gt;50% stenosis</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

**Engage EC**

**Stop Short**
AP and Lateral Imaging Confirms Sheath Position

AP View – Arterial Sheath Tip
(Radiopaque distal 4mm)
Centrally positioned in the lumen of CCA

Lateral View – Arterial Sheath Tip
Ensures robust reverse flow and minimizes risk of posterior wall dissection from tip and interventional device exchanges
Blood flow is temporarily reversed in the carotid arteries.

Working channel for interventional devices.

Blood flow is returned to femoral vein.

ENROUTE® Transcarotid Stent System (57cm).

Dynamic Flow Controller & Integrated 200µ Filter High / Low / Stop.
Post-Op Management

DAPT and Statins

- Aspirin indefinitely
- Clopidogrel and Statin Therapy for a minimum of 4 weeks

Blood Pressure Management

- Continuously monitor BP for 24 hours
- Avoid hypertension/hyperperfusion (<20% baseline systolic)
- Avoid hypotension/hypoperfusion (≤90mmHg)
Reverse Flow Intolerance (0.7% in ROADSTER 1)

**Table II. Step-wise management of neurological intolerance**

<table>
<thead>
<tr>
<th>Order of successive suggested step</th>
<th>Suggested management</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Ensure balloons and stents are prepared in advance to limit time on flow reversal</td>
</tr>
<tr>
<td>2</td>
<td>Provide supplemental oxygen and elevate systolic blood pressure &gt;160 mm Hg (plus avoidance of conscious sedation)</td>
</tr>
<tr>
<td>3</td>
<td>Switching the flow controller to “Low” with continued monitoring of the patient and, if tolerated, alternating to high flow during key interventional steps (alternatively, the procedure can be completed on “Low” flow)</td>
</tr>
<tr>
<td>4</td>
<td>Ischemic preconditioning: temporarily halting the procedure and re-establishing antegrade flow by releasing control of the CCA inflow for 5 minutes and then reclamping</td>
</tr>
<tr>
<td>5</td>
<td>Expeditious completion of the procedure on “High” flow (if there is no focal neurological deficit)</td>
</tr>
<tr>
<td>6</td>
<td>Convert to GA (lower cerebral metabolic demand) and complete expeditiously</td>
</tr>
<tr>
<td>7</td>
<td>If all above fails, the operator should consider abandoning flow reversal and employing a distal embolic protection filter.</td>
</tr>
</tbody>
</table>

*GA, General anesthesia; CCA, common carotid artery.*
When to use TCAR?

**Indications**
- All high surgical risk patients
  - arch avoidance = less stroke
- Constant embolic protection from start to finish
  - No unprotected lesion manipulation
- Superlative outcomes in high risk populations
  - Elderly
  - Female
  - Symptomatic

**Contraindications**
- Diffuse/severe disease in the CCA
- Short CCA runway from clavicle to bifurcation (<5cm)
- CCA reference diameter ≤6mm
Conclusions

TCAR is safe and effective in patients with multiple anatomic and physiologic risk factors.

Diligent and meticulous access is the key to achieving successful outcomes with TCAR.

There are very few absolute contraindications to the use of TCAR.
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