Transcarotid Artery Revascularization (TCAR) Procedure

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TCAR
Protection from stroke
And so much more
Up to 1/3 of strokes are from carotid origin¹

**STROKE** IS A LEADING CAUSE OF **DEATH** IN THE UNITED STATES

Nearly 800,000 people in the United States have a stroke every year, with about three in four being first-time strokes.²

¹ Source: Society of Vascular Surgery’s Patient Resources, for further information and disclaimer: https://vascular.org/patient-resources/vascular-conditions/carotid-artery-disease
² Source: https://www.ahajournals.org/doi/10.1161/STROKEAHA.114.005090
HOW DOES CAROTID ARTERY DISEASE CAUSE STROKE?

Cause of stroke:
Fragments break off and move to brain
Challenge of Stroke Prevention

Most carotid disease is silent – often, the first symptom a patient has is a stroke.
Challenge of Stroke Prevention

It is estimated that for every symptomatic stroke, there are nearly fourteen ‘silent’ strokes that may result in changes to cognitive function and processes.
ACC/AHA CAROTID SCREENING GUIDELINES

• Symptomatic (neurologic event)
• Carotid Bruit
• Evidence of Vascular Disease
  – Coronary artery disease
  – Peripheral artery disease
  – Aortic aneurysm
• >2 Atherosclerotic Risk Factors
  – Hypertension
  – Hyperlipidemia
  – Smoking history
  – Family history of stroke

Joint Recommendations by 2011 American College of Cardiology Foundation/American Heart Association Task Force et al. - Guidelines on the management of patients with Extracranial Carotid and Vertebral Artery Disease
**SURGICAL:**
Carotid Endarterectomy (CEA)
65+ years

〜83% of procedures

SIGNIFICANT adverse events

LOW 30-day stroke risk

CREST MI¹: 2.3% CEA vs 1.1% TF CAS
CREST CNI²: 2.1% CNI unresolved at 6 months (80% motor)

**ENDOVASCULAR:**
Transfemoral Carotid Artery Stenting (CAS)
Since the ‘90s

〜10% of procedures*

LOWER adverse events

HIGHER (〜2x) 30-day stroke risk

CREST 30-day All Stroke¹: 2.3% CEA vs 4.1% TF CAS

Source: Modus Health Group *Excludes TCAR procedures
TCAR PARADIGM SHIFT: TRANSCAROTID

TCAR combines advantages from both worlds: **surgical principles** of neuroprotection and game-changing **endovascular technology**

- Minimally Invasive
- Avoids Aortic Arch
- Avoids Cranial Nerve Plexus
- High-Rate Flow Reversal Neuroprotection
- Accurate stenting


Caution: Federal (USA) 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.
WHAT IS TCAR?
Blood flow is temporarily reversed in the carotid arteries.

Working channel for interventional devices.

ENROUTE® Transcarotid Stent System (57cm)

Dynamic Flow Controller & Integrated 200µ Filter High / Low / Stop

Blood flow is returned to femoral vein.

ENROUTE® TRANSCAROTID NEUROPROTECTION & STENT SYSTEM
The stroke rate of 0.6% after TCAR in the Per Protocol population may be the lowest reported rate after any carotid intervention.

– Stroke 2020; 51:2620–2629

PROOF: J Endovasc Ther. 2017 Apr;24(2):265-270
ROADSTER 2: Trial Results – Stroke. 2020;51:2620–2629; Kashyap V, Schneider P. Outcomes of TransCarotid Revascularization with dynamic flow reversal (TCAR) versus carotid endarterectomy (CEA) in the TCAR Surveillance Project – M. Malas, Annals of Surgery 2020

Protection from stroke
And so much more
TCAR VS TF-CAS IN THE VQI DATABASE\(^1\)

The authors reviewed patient data (\(n = 3286\) matched) collected from the VQI-TSP to compare outcomes of TCAR vs TF-CAS; published in the *Journal of the American Medical Association* (JAMA).

**TCAR Safety**
The investigators found a significant decrease in stroke, death, and stroke/death for patients who underwent TCAR.

**Durability and Efficiency**
The investigators found a significant decrease in stroke or death at one year as well as procedural efficiencies with TCAR.

**Conclusion:** TCAR had a *significantly lower* risk of stroke or death compared to TF-CAS with improved procedural efficiencies (radiation/contrast).

<table>
<thead>
<tr>
<th></th>
<th>IN-HOSPITAL STROKE OR DEATH</th>
<th>STROKE</th>
<th>DEATH</th>
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</thead>
<tbody>
<tr>
<td>TCAR</td>
<td>1.60%</td>
<td>1.30%</td>
<td>0.40%</td>
</tr>
<tr>
<td>TF-CAS</td>
<td>3.10%</td>
<td>2.40%</td>
<td>1.00%</td>
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<table>
<thead>
<tr>
<th></th>
<th>RADIATION EFFICIENCY</th>
<th>CONTRAST EFFICIENCY</th>
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<tbody>
<tr>
<td>TCAR</td>
<td>5 mins</td>
<td>30 ml</td>
</tr>
<tr>
<td>TF-CAS</td>
<td>16 mins</td>
<td>80 ml</td>
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WHEN RECEIVING TCAR VS CEA, A PATIENT IS…

86% Less Risk of CNI

47% Less Risk of MI

48 mins Shorter OR Time

12% less likely to have an extended stay past one day
TRANSCAROTID ARTERY REVASCULARIZATION (TCAR)

A Less Invasive Way To Prevent Stroke

CEA

smaller incision

TCAR
## STANDARD POST-PROCEDURE MEDICATIONS

Dual antiplatelet therapy and statin*

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<tr>
<th>Medication</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Aspirin</strong></td>
<td>75-325 mg/day continued indefinitely</td>
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<tr>
<td><strong>Plavix®</strong></td>
<td>(Clopidogrel) or equivalent 75 mg/day for at least 4 weeks post-procedure</td>
</tr>
<tr>
<td><strong>Statin</strong></td>
<td>Therapeutic dose for at least 4 weeks post-procedure</td>
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*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 - https://www.ahajournals.org/doi/pdf/10.1161/CIR.0b013e31820d8d78

Violation of medication regimen is #1 cause of MAE in TCAR
PATIENT TESTIMONIAL-DR. WILSON’S STORY