Technical Tips for Optimizing Outcomes with TCAR: Precautions And Contraindications To Its Use: Does It Decrease Stroke Rates (From the SVS Registry)

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Presenter Disclosure Information

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1. CREST
2. ACT I
3. CAPTURE II
4. CHOICE
5. FREEDOM
6. ROADSTER
7. SAPHIRE W
8. ROADSTER II
9. CREST II
10. CREST Companion Study
11. ROADSTER Long-Term Follow up Study

Proctor: Training vascular surgeons how to perform TCAR safely

TCAR Indications and Contraindications:
Focus on Safe Access

Instructions for Use
EMBOSITE Transendural Neuronomodulation System (TNS)

Indications for Use
The EMBOSITE Transendural Neuron modulation System (TNS) is intended to provide transient, vascular access, intervention in the proximal neck, and selective, controlled occlusion of the innominate artery using a flexible, antecubital, and/or femoral access system. The EMBOSITE system is indicated for use in patients who would otherwise require open surgical access to the innominate artery for diagnostic or therapeutic purposes.

Contraindications
The EMBOSITE TNS is contraindicated for use in patients exhibiting the following conditions:
- Patients with severe anemia
- Patients with prior radiation therapy to the neck
- Patients with prior intravascular stents
- Patients with prior carotid endarterectomy

Imaging considerations
- CCA Depth/landing zone < 1

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Anatomic Contraindications
- Back wall atheroma
- Circumferential atheroma

Patient head and neck in position to be used during surgery
Pre procedure medications

Dual antiplatelet therapy

- **Aspirin**
  - Optimal: 75-325 mg/day at least 7 days pre procedure
  - Loading dose: 325 mg of aspirin provided that it is non-enteric coated at least 6 hours prior to procedure

- **Plavix (Clopidogrel) or equivalent**
  - Optimal: 75 mg/day at least 7 days pre procedure
  - Loading dose: 650 mg Plavix loading dose at least 6 hours prior to procedure

Statin Therapy

- Optimal: Therapeutic dose at least 7 days pre procedure
- Loading Dose: at least 12 hours prior to procedure

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
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</thead>
<tbody>
<tr>
<td>Atorvastatin (Lipitor®)</td>
<td>40 mg</td>
</tr>
<tr>
<td>Rosuvastatin (Crestor®)</td>
<td>20 mg</td>
</tr>
<tr>
<td>Simvastatin (Zocor®)</td>
<td>80 mg</td>
</tr>
<tr>
<td>Ezetimibe / simvastatin (Vytorin®)</td>
<td>10/20 mg</td>
</tr>
</tbody>
</table>

Statin users had 63% reduction in mortality in patients who developed major complications following CAS (OR 0.37, 95%CI: 0.22-0.61, P-value <0.001)

Blood Pressure Management

- TCAR minimizes the number of events of labile BP or HR.
- However, appropriate BP control is essential to maintain robust flow reversal and neuroprotection.
- **During flow reversal:** SBP between 140 and 160 mm Hg
- **Postoperatively:** SBP between 100 and 140 mm Hg

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 the jugular vein partially dissected and retracted medially
5. A 3-4 cm segment of the proximal CCA is dissected circumferentially followed by vessel loop to control the CCA

Pre-Suture Artery – TCAR

- Pre-close with "U" or "Z" or Purse String stitch using a 5-0 or 6-0 polypropylene suture
- Do not puncture the CCA
- Administer heparin to provide systemic anticoagulation
  - Target ACT of >250 seconds
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.

Arterial ACCESS
STOP SHORT Technique
- Critical to Stop Short when disease is present in the CCA and bifurcation.
- Caution: Disease in the distal CCA is often under-appreciated.

CCA Access
Engage the EC technique
- Engage External Carotid (EC)
  - CCA is 5-7cm & prox EC is clear or
  - CCA is 5-7cm & prox EC <50% stenosis without significant angulation at EC origin.

Reduce risk of CCA Dissection
- Careful micro puncture access.
- Engage ECA whenever possible.
- Dilate anterior surface of CCA with 6 & 9 Fr dilators.
- One spot fluoroscopy to confirm wire position still in position prior to inserting the 8.5 Fr Sheath.

Transcarotid Stenting with Dynamic Flow Reversal
- Avoid the arch.
- “CEA-like” neuroprotection.
- Less manipulation.
- Predictable, efficient.

Dynamic Flow Reversal For ROBUST Neuroprotection
- Direct carotid access reduces embolic risks of transfemoral catheter advancement.
- Continuous high rate of flow reversal to remove debris throughout intervention.
Intraoperative Techniques

- Pre-stent angioplasty only
- Single close cell stent from CCA to ICA
- Do not balloon the stent

Compared with pre-SB alone, the use of post-SB increases the chances of perioperative HD and stroke and death rate (OR: 2.37, 95% CI: 1.01-5.62, p<0.05)

TCAR Surveillance Project (TSP)
Objectives of TSP

Provide "REAL-WORLD" Outcomes

- Monitor the safety and effectiveness of stents placed directly into the carotid artery while reversing blood flow within the carotid artery to reduce stroke risk.

- Compare this less-invasive surgical procedure with standard carotid endarterectomy in centers that participate in the Society for Vascular Surgery Vascular Quality Initiative.

Take Home Points

- TCAR is a promising hybrid procedure with excellent outcomes
- There are several important technical tips for safe TCAR
- Outcomes from real world are in-line with the initial IDA and post-approval trials