

## Why We Need An RCT Comparing TCAR With TFCAS, Transradial CAS And Best Medical Treatment For ACS And Symptomatic Carotid Stenosis

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Friday 4:06 PM - 4:11 PM Session 85

## Financial Disclosures

- There is nothing to report
- Owner of several patents in the carotid aspiration and filtration field

## Why We Need A RCT Comparison Of TCAR With TFCAS, Transradial CAS And Best Medical Treatment For ACS And Symptomatic Carotid Stenosis


- We Still Would Like to Know:
  - Best Treatment(s) for Asymptomatic Cervical Carotid Patients?
  - How Good is Best Medical Therapy now?
  - How does TCAR really compare to CEA and CAS?


## 2023 CMS Expansion of Carotid Stenting

- **PATIENT/PHYSICIANS WILL NOW HAVE CHOICES:**



## 2024: NEED FOR MORE INFORMATION

- Over 30 Registries and Trials since 2002
  - Common thoughts:
    - "We do not need more trials to show very little difference b/n CAS and CEA" 
- Improvements in Best Medical Therapy
  - Age of Statins and Semaglutides (GLP-1)
  - Impact on Cervical Carotid Disease



## Rapid Rise of TCAR


- 2015 FDA approved TCAR to treat high-risk patients and later in 2022 for standard-risk patients
  - This approval was granted through corporate sponsored registries in the absence of a dedicated randomized trial comparing it to BMT or other procedures.
  - TCAR has since been rapidly adopted into practice and now accounts for ≈1 in 4 carotid procedures across the 606 US centers

## Issues Medical Community Have with TCAR Data

- No Adjudicated Data
- No RCT
- No Independent Neurology Review
- Hidden Complications:
  - Non-reported complications of pneumothorax, neck hematoma, and common carotid artery stenosis
  - Misplacement of stent 15%
- Higher Cost:
  - \$22,315 TCAR vs \$11,001 CAS

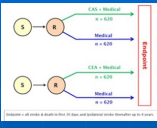
## Why No TCAR in Europe?

- Recently, Silk Road Medical decided to completely withdraw TCAR from the European market.
  - Lack of 30-Day Complications
    - VQI data are limited to in-hospital endpoints, which underestimate procedural risks by 20-25%
  - Lack of Long-Term Data
    - Roadster-2 reported 0% strokes at one year, but only 1/5 of the 155 patients participated.
  - Missing Key Areas
    - Exclusions Unreported: Up to one-third of patients are anatomically unsuitable for TCAR due to calcification or tortuosity



## Waiting for CREST-2

- Two Arms.
  - 97% Finished-Results 2026
- TCAR not included in CREST-2
  - TCAR is slightly different than the two, so it cannot truly be accommodated into either arm
- So What about a CREST-3 ?
  - TCAR vs CAS vs CEA with BMT
  - BEACH-2 ?



## The Problem: SVS VQI Does not believe in RCT

Society for Vascular Surgery Vascular Quality Initiative:

**VQI – Past, Present and Future**  
My View – Jens Eldrup-Jorgensen

"Big data is said to be the wave of the future allowing us to extract and analyze data"

FDA believes that registry-based trials are the future of device approval and post-market surveillance throughout the total product life cycle.<sup>25</sup> Randomized clinical trials (RCT) are felt to be of decreasing value as they are performed by selected providers at selected centers on selected patients and may not be generalizable and reflect real world outcomes.<sup>26</sup> In addition, RCT are becoming increasingly complex with increasing regulatory challenges and increasing expense resulting in delay to market. Registry-based RCT are felt to provide real world evidence that can support regulatory decision making in a cost effective manner.<sup>27</sup>

## Grades of Recommendation

So If We Follow the SVS VQI Guidelines, We Will Never Have Level 1a or 1b Evidence Ever Again?

B	2a	Systematic review of (homogeneous) cohort studies of "exposed" and "unexposed" subjects
B	2b	Individual cohort study / low-quality randomized control studies
B	3a	Systematic review of (homogeneous) case-control studies
B	3b	Individual case-control studies
C	4	Case series, low-quality cohort or case-control studies
D	5	Expert opinions based on non-systematic reviews of results or mechanistic studies

## Really, Are Registries Better?

1997 World Carotid Registry

**Current global status of carotid artery stent placement**

**N=2,048**  
All Stroke and Death Rate 5.7%

2003 World Carotid Registry

**PERIPHERAL VASCULAR DISEASE**

**Original Studies**

**Updated Review of the Global Carotid Artery Stent Registry**

**N=11,243**  
All Stroke and Death Rate 4%  
3-Yr Follow up 1.7% Stroke

## Why Would TCAR Take a Chance with a RCT?

- TCAR already has FDA approval for standard and high risk symptomatic and asymptomatic carotid disease
  - Market Share in US - 70%
  - Which is a pity for there are some great studies coming out:

From the Southern Association for Vascular Surgery

**Clinical outcomes of transcatheter artery revascularization vs carotid endarterectomy from a large single-center experience**

Ali F. AbuRaddwan, MD<sup>1</sup>, Jackson Santos, MD<sup>2</sup>, Zachary T. Abulafia, DO<sup>1</sup>, Andrew Lee, MD<sup>1</sup>, Christina Veith, DO<sup>1</sup>, Noah Sarge, MD<sup>1</sup>, Robert Crispin, MD<sup>1</sup>, Scott Davis, PhD, MBA<sup>1</sup>, and Elaine Mattson, RN, ELS<sup>1</sup>, Charleston, SC

CENTRAL, VASCULAR


**Procedural Safety Comparison Between Transcatheter Artery Revascularization, Carotid Endarterectomy, and Carotid Stenting: Perioperative and 1-Year Rates of Stroke or Death**

James A. Gosselin, MD, MCh<sup>1</sup>, Peter Michael Cantone, PhD<sup>2</sup>, David N. Sacks, MD, PhD<sup>1</sup>, Anthony M. Hsu, MD, PhD<sup>1</sup>, and Charles E. Hayes, MD<sup>1</sup>

## PREDICTING THE FUTURE OF CAROTIDS



## Conclusion

- Why a RCT is needed for TCAR?
  - It is the right thing to do. 
    - Need for Clinical Equipolse
  - The science has been lacking
    - TCAR has been faulted by extremely limited trials
      - Corporate sponsored
  - The new data and personal experiences with Direct Carotid Access and TCAR are encouraging and need further exploration

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## Thank you, Frank

