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Creating a world without heart and vascular disease

Carotid Artery Disease… (Almost) Everything I Need to Know for 2021

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Disclosures

- Silk Road Medical (TCAR)
  - Site PI: ROADSTER and ROADSTER-2
  - Physician Education/Training/Certification
- Medtronic
  - Physician/Trainee Education
- Endospan
  - Chair, Clinical Events Committee (TRIOMPHE)

- No discussion of "off label" devices/techniques
- Opinions are my own and do not represent official societal/committee endorsements

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Learning Objective

- Understand the epidemiology and pathophysiology of carotid artery disease
- Describe the advantages and risks with endarterectomy and stent placement
  - Discussion on TF-CAS vs TCAR
- Explain the rationale for carotid revascularization in select patients
  - Focus on asymptomatic carotid stenosis

Epidemiology of Stroke

- 5th leading cause of death in US (2018)
  - Heart, cancer, unintentional injuries, respiratory disease
  - 2007 to 2017, age-adjusted stroke death decreased 13.6% and actual number declined 7.7%
  - 146,383 people (1 of 19 deaths)
- Leading cause of serious long term disability (~$45.5B in 2014-15)
  - health care services, medications, missed days of work
- 795,000 new strokes per year
  - 610K first attacks, 185K recurrent attacks
- US: Stroke (every 40 seconds); Death (every 3 min 35 sec)

- Heart Disease and Stroke Statistic-2020 Update: A Report from the American Heart Association. Circulation 2020.
- Mortality in the United States, 2018: NCHS Data Brief, No 355, January 2020

Epidemiology of Stroke

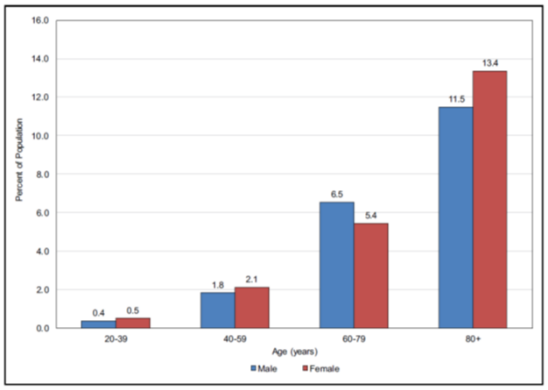
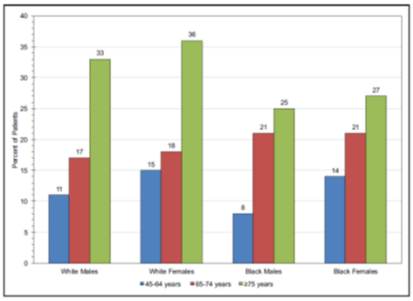


Chart 14-1. Prevalence of stroke by age and sex, United States (NHANES, 2013–2016).
NHANES indicates National Health and Nutrition Examination Survey.
Source: Unpublished National Heart, Lung, and Blood Institute tabulation using NHANES, 2013 to 2016.[398]

Epidemiology of Stroke



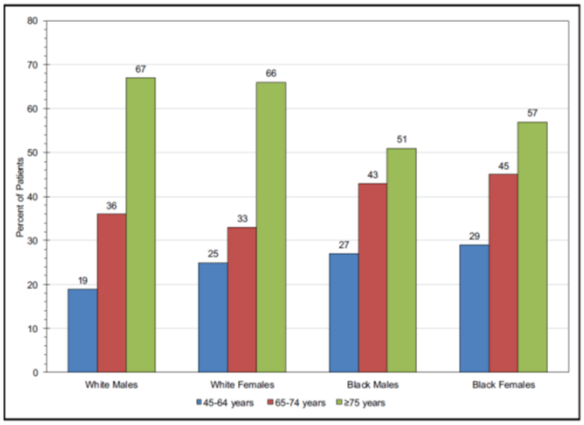
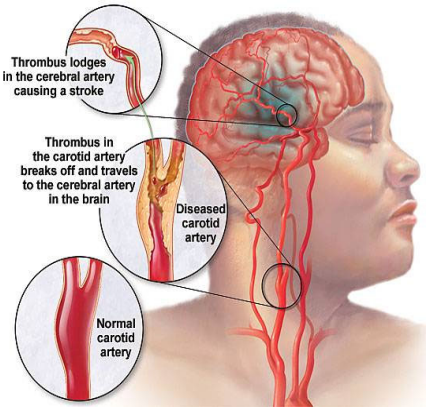


Chart 14-7. Probability of death within 1 year after first stroke, United States, 1995 to 2011.*
Chart 14-8. Probability of death within 5 years after first stroke, United States, 1995 to 2011.*

Pathophysiology of Stroke

- 87% of stroke are ischemic (10% ICH; 3% SAH)
- 15-30% secondary to extracranial internal carotid artery disease



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Symptomatic Carotid Artery Disease

- TIA (transient ischemic attack) – "crescendo"
- Amaurosis fugax (ophthalmic artery)
- Stroke – "stroke in evolution"

- Must correlate with symptom/cerebral territory with carotid disease

- Syncope (on if ***severe***, ***bilateral*** disease)
- Other clinical conditions likely ***not*** associated with carotid artery disease
  - Unconsciousness, seizures, vertigo
  - Incontinence, amnesia, memory loss, forgetfulness, dementia

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Asymptomatic Carotid Stenosis

- Overall prevalence in general population is low, but increases with age

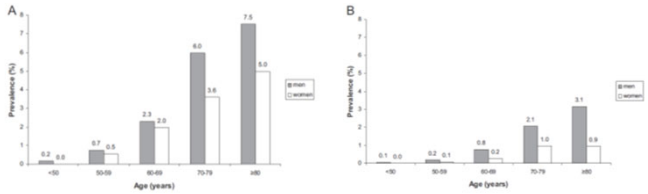

Figure 1. Age- and sex-specific prevalence estimates of moderate (A) and severe ACAS (B) in men and women.

de Weerd M, et al. Stroke 2010;41:1294-1297

- Associated w/cardiovascular risk factors (HTN, DM, HC, tobacco)
- Estimated risk of stroke 0.5-1%/year
  - Preceded by TIA?
- No linear correlation between degree of stenosis and stroke risk

Screening for Asymptomatic Carotid Stenosis

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

CLASS IIa
Benefit >> Risk
Additional studies with focused objectives needed
IT IS REASONABLE to perform procedure/administer treatment

1. It is reasonable to perform duplex ultrasonography to detect hemodynamically significant carotid stenosis in asymptomatic patients with carotid bruit. *(Level of Evidence: C)*

CLASS IIb
Benefit ≥ Risk
Additional studies with broad objectives needed; additional registry data would be helpful
Procedure/Treatment **MAY BE CONSIDERED**

1. Duplex ultrasonography to detect hemodynamically significant carotid stenosis may be considered in asymptomatic patients with symptomatic peripheral arterial disease (PAD), coronary artery disease, or atherosclerotic aortic aneurysm, but because such patients already have an indication for medical therapy to prevent ischemic symptoms, it is unclear whether establishing the additional diagnosis of ECVD in those without carotid bruit would justify actions that affect clinical outcomes. *(Level of Evidence: C)*
2. Duplex ultrasonography might be considered to detect carotid stenosis in asymptomatic patients without clinical evidence of atherosclerosis who have 2 or more of the following risk factors: hypertension, hyperlipidemia, tobacco smoking, a family history in a first-degree relative of atherosclerosis manifested before age 60 years, or a family history of ischemic stroke. However, it is unclear whether establishing a diagnosis of ECVD would justify actions that affect clinical outcomes. *(Level of Evidence: C)*

Screening for Asymptomatic Carotid Stenosis

- July 8, 2014 USPSTF Recommendation
  - 2020-21: Update in Progress

U.S. Preventive Services TASK FORCE

SCREENING FOR ASYMPTOMATIC CAROTID ARTERY STENOSIS
CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

Population	Adults without a history of transient ischemic attack, stroke, or other neurologic signs or symptoms
Recommendation	Do not screen for asymptomatic carotid artery stenosis in the general adult population. Grade: D

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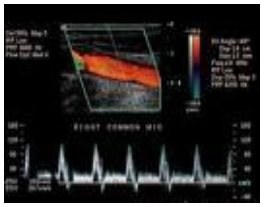
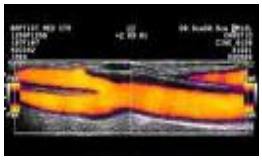
Diagnosis of Carotid Artery Disease

- Duplex ultrasound
  - Low cost, noninvasive
  - Velocity criteria (cm/s)

Stenosis	PSV	EDV	IC/CC
<50%	<125	<40	<2.0
50-69%	125-230	40-100	2.0-4.0
≥70%	>230	>100	>4.0

  - Technician dependent
  - Limited anatomic information
  - Use for initial diagnosis, longitudinal follow-up





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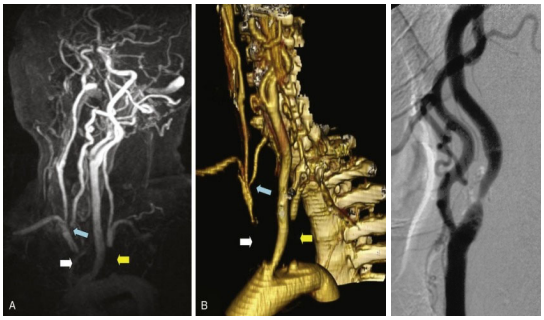
Diagnosis of Carotid Artery Disease

- Cross Sectional Imaging (CT/MR)
  - Higher cost, contrast utilization
  - Additional anatomic information
    - Arch anatomy
    - Circle of Willis
  - Accuracy affected by calcification/artifact

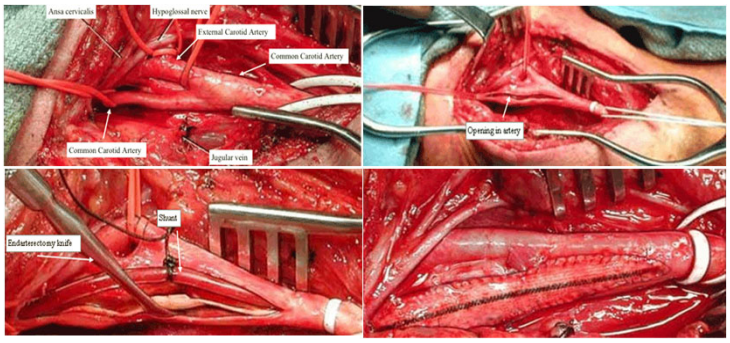
- Contrast Angiography
  - "Gold standard"
  - Invasive procedure, access complications
  - Periprocedural risk of stroke ("1%")

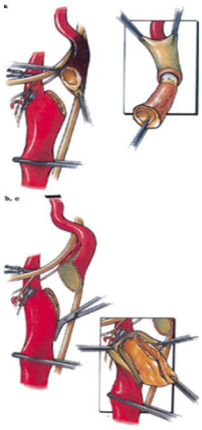


Treatment of Carotid Artery Disease

- Medical Management: "best practice" for all patients
  - Antiplatelet therapy
  - Aggressive statin therapy
  - Management of comorbid conditions
    - Hypertension
    - Diabetes
  - Lifestyle modification
    - Smoking cessation

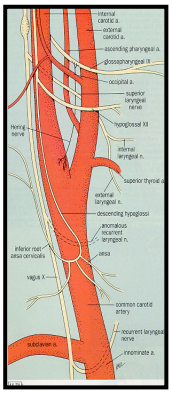
Carotid Endarterectomy (CEA)





Complication After CEA

- Postoperative stroke/death/MI
  - AHA guidelines: 30 day stroke/death (<3% ASX; 6% SX)
- Exploration for bleeding (1-4%); wound infection (<1%)
- Cranial nerve injury (palsy vs permanent)
  - Vagus, hypoglossal, facial nerves
  - Significantly decreased from 8% to <2%
  - Fewer than 1/7 are permanent
- Hyperperfusion syndrome (BP control)
- Recurrent stenosis (6% in 2 years)



- Cranial Nerve Injury After Carotid Endarterectomy: Incidence, Risk Factors and Time Trends. Eur J Vasc Endovasc Surg 2017.

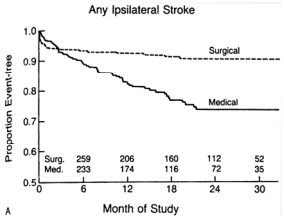
Evidence for CEA (Symptomatic)

- NASCET trial (***>50% stenosis*** for ***symptomatic*** patients)

Volume 325 AUGUST 15, 1991 Number 7

BENEFICIAL EFFECT OF CAROTID ENDARTERECTOMY IN SYMPTOMATIC PATIENTS WITH HIGH-GRADE CAROTID STENOSIS

North American Symptomatic Carotid Endarterectomy Trial Collaborators*



- ***70-99%*** (26% vs 9%, 2 years)

BENEFIT OF CAROTID ENDARTERECTOMY IN PATIENTS WITH SYMPTOMATIC MODERATE OR SEVERE STENOSIS

(N Engl J Med 1998;339:1415-25.)

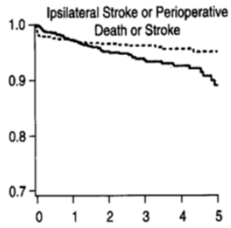
- ***50-69%*** (15.7% vs 22.2%, 5 years)

Evidence for CEA (Asymptomatic)

- ACAS/ACST trial (***>60% stenosis*** for ***asymptomatic*** patients)

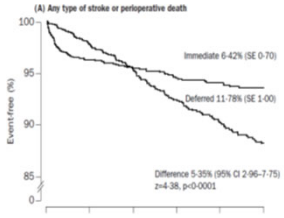
Endarterectomy for Asymptomatic Carotid Artery Stenosis

Executive Committee for the Asymptomatic Carotid Atherosclerosis Study (*JAMA.* 1995;273:1421-1428)



Prevention of disabling and fatal strokes by successful carotid endarterectomy in patients without recent neurological symptoms: randomised controlled trial

*MRC Asymptomatic Carotid Surgery Trial (ACST) Collaborative Group** *Lancet* 2004; **363:** 1491–502



"High Risk" For CEA

- Patients at potential for higher risk for complications during CEA

ANATOMIC HIGH RISK

- Prior head/neck surgery or irradiation
- Spinal immobility
- Restenosis post CEA
- Surgically inaccessible lesion
- Laryngeal palsy; Laryngectomy
- Permanent contralateral cranial nerve injury
- Contralateral occlusion
- Severe tandem lesions
- Bilateral stenosis requiring treatment

PHYSIOLOGIC HIGH RISK

- Age ≥75
- Congestive Heart Failure
- Left Ventricular Ejection Fraction ≤35%
- ≥2 diseased coronaries with ≥70% stenosis
- Unstable angina
- Myocardial infarction within 6 weeks
- Abnormal stress test
- Need for open heart surgery
- Need for major surgery (including vascular)
- Uncontrolled diabetes
- Severe pulmonary disease

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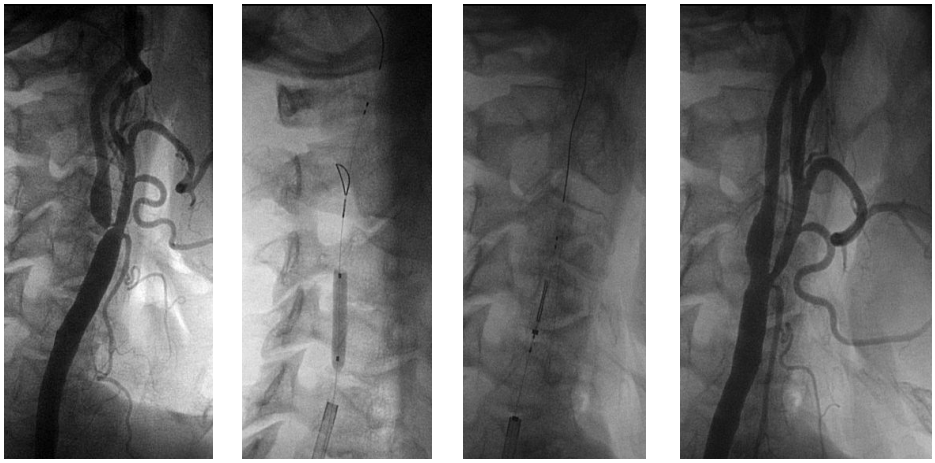
Carotid Angioplasty and Stenting (*TF*-CAS)



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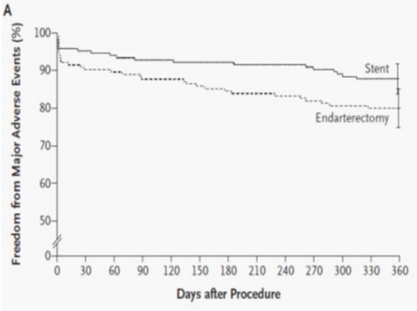
Evidence for *TF*-CAS (High Risk Patients)

Protected Carotid-Artery Stenting versus Endarterectomy in High-Risk Patients

N Engl J Med 2004;351:1493-501.



March 2005 (CMS NCD)

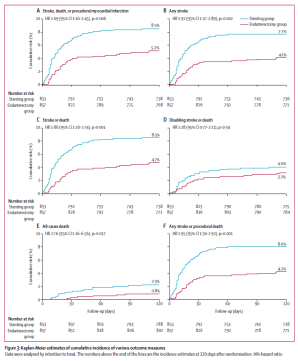
- High risk, symptomatic, >70% stenosis
- Additional allowances for clinical trials

ICSS (*TF*-CAS)

Carotid artery stenting compared with endarterectomy in patients with symptomatic carotid stenosis (International Carotid Stenting Study): an interim analysis of a randomised controlled trial

*International Carotid Stenting Study investigators**

Lancet 2010; 375: 985-97



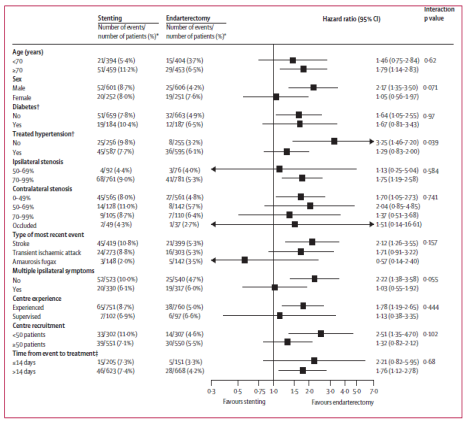


Figure 4: Subgroup analysis to compare the rates of stroke, death, or procedural myocardial infarction in different subgroups

- Suitable for both CEA/CAS
- Experience: 50 total (10/yr)

CREST (*TF*-CAS)

Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis

N Engl J Med 2010;363:11-23.

- Suitable for both CEA/CAS
- "Lead-in" phase for physicians

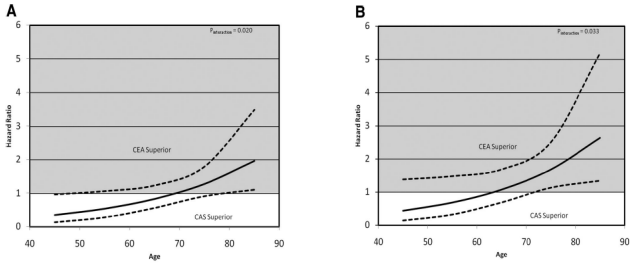
Table 2. Primary End Point, Components of the Primary End Point, and Other Events, According to Treatment Group.*

End Point	Periprocedural Period				
	CAS (N=1262)	CEA (N=1240)	Absolute Treatment Effect of CAS vs. CEA (95% CI)	Hazard Ratio for CAS vs. CEA (95% CI)	P Value
	no. of patients (% ±SE)		*percentage points*		
Death	9 (0.7±0.2)	4 (0.3±0.2)	0.4 (−0.2 to 1.0)	2.25 (0.69 to 7.30)†	0.18†
Stroke					
Any	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major ipsilateral	11 (0.9±0.3)	4 (0.3±0.2)	0.5 (−0.1 to 1.2)	2.67 (0.85 to 8.40)	0.09
Major nonipsilateral‡	0	4 (0.3±0.2)	NA	NA	NA
Minor ipsilateral	37 (2.9±0.5)	17 (1.4±0.3)	1.6 (0.4 to 2.7)	2.16 (1.22 to 3.83)	0.009
Minor nonipsilateral	4 (0.3±0.2)	4 (0.3±0.2)	0.0 (−0.4 to 0.4)	1.02 (0.25 to 4.07)	0.98†
Myocardial infarction	14 (1.1±0.3)	28 (2.3±0.4)	−1.1 (−2.2 to −0.1)	0.50 (0.26 to 0.94)	0.03
Any periprocedural stroke or postprocedural ipsilateral stroke	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major stroke	11 (0.9±0.3)	8 (0.6±0.2)	0.2 (−0.5 to 0.9)	1.35 (0.54 to 3.36)	0.52
Minor stroke	41 (3.2±0.5)	21 (1.7±0.4)	1.6 (0.3 to 2.8)	1.95 (1.15 to 3.30)	0.01
Any periprocedural stroke or death or post-procedural ipsilateral stroke	55 (4.4±0.6)	29 (2.3±0.4)	2.0 (0.6 to 3.4)	1.90 (1.21 to 2.98)	0.005
Primary end point (any periprocedural stroke, myocardial infarction, or death or postprocedural ipsilateral stroke)	66 (5.2±0.6)	56 (4.5±0.6)	0.7 (−1.0 to 2.4)	1.18 (0.82 to 1.68)	0.38

CREST (*TF*-CAS)

End Point	4-Yr Study Period (Including Periprocedural Period)				
	CAS (N=1262)	CEA (N=1240)	Absolute Treatment Effect of CAS vs. CEA (95% CI)	Hazard Ratio for CAS vs. CEA (95% CI)	P Value
	no. of patients (% ±SE)		*percentage points*		
Death	94 (11.3±1.2)	83 (12.6±1.5)	−1.3 (−5.1 to 2.5)	1.12 (0.83 to 1.51)	0.45
Stroke					
Any	105 (10.2±1.1)	75 (7.9±1.0)	2.3 (−0.6 to 5.2)	1.40 (1.04 to 1.89)	0.03
Major ipsilateral	16 (1.4±0.3)	6 (0.5±0.2)	0.8 (0.1 to 1.6)	2.56 (1.00 to 6.54)	0.05
Major nonipsilateral‡	6 (0.9±0.4)	8 (0.8±0.3)	0.1 (−0.9 to 1.1)	0.73 (0.25 to 2.11)	0.56†
Minor ipsilateral	52 (4.5±0.6)	36 (3.5±0.6)	1.0 (−0.7 to 2.7)	1.43 (0.94 to 2.19)	0.10
Minor nonipsilateral	33 (4.0±0.8)	29 (3.8±0.9)	0.2 (−2.1 to 2.4)	1.11 (0.67 to 1.82)	0.69
Myocardial infarction					
Any periprocedural stroke or postprocedural ipsilateral stroke	72 (6.2±0.7)	50 (4.7±0.7)	1.5 (−0.4 to 3.4)	1.44 (1.00 to 2.06)	0.049
Major stroke	16 (1.4±0.3)	10 (0.8±0.3)	0.6 (−0.2 to 1.4)	1.55 (0.70 to 3.42)	0.28
Minor stroke	56 (4.8±0.6)	40 (3.8±0.6)	1.0 (−0.8 to 2.7)	1.39 (0.93 to 2.09)	0.11
Any periprocedural stroke or death or post-procedural ipsilateral stroke	75 (6.4±0.7)	50 (4.7±0.7)	1.7 (−0.2 to 3.7)	1.50 (1.05 to 2.15)	0.03
Primary end point (any periprocedural stroke, myocardial infarction, or death or postprocedural ipsilateral stroke)	85 (7.2±0.8)	76 (6.8±0.8)	0.4 (−1.7 to 2.6)	1.11 (0.81 to 1.51)	0.51

CREST (*TF*-CAS)



- "efficacy of CAS and CEA approximately ~ at age 70"
- Stroke: equal risk at ~64 years
- Periprocedural risk higher in women (CAS)
- No difference by symptomatic status; Restenosis similar after 2 years (6%)

ACT-1 (*TF*-CAS)

Randomized Trial of Stent versus Surgery for Asymptomatic Carotid Stenosis

N Engl J Med 2016;374:1011-20.

- age<80, >70% stenosis, asymptomatic, not high risk
- 1453 patients: 3:1 CAS:CEA
- "lead in phase"
- 1º endpoint: 3.8% CAS vs 3.4% CEA
- 30d S/D: 2.9% CAS vs 1.7% CEA
- 5y FF S: 93.1 CAS vs 94.7% CAS
- CAS "noninferior" to CEA

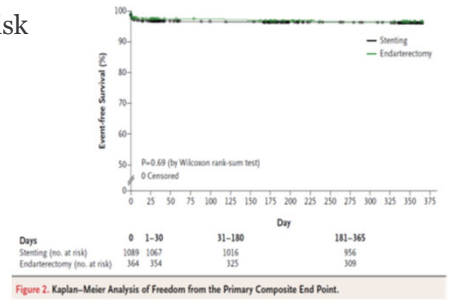


Figure 2. Kaplan–Meier Analysis of Freedom from the Primary Composite End Point.

Carotid Revascularization in the US

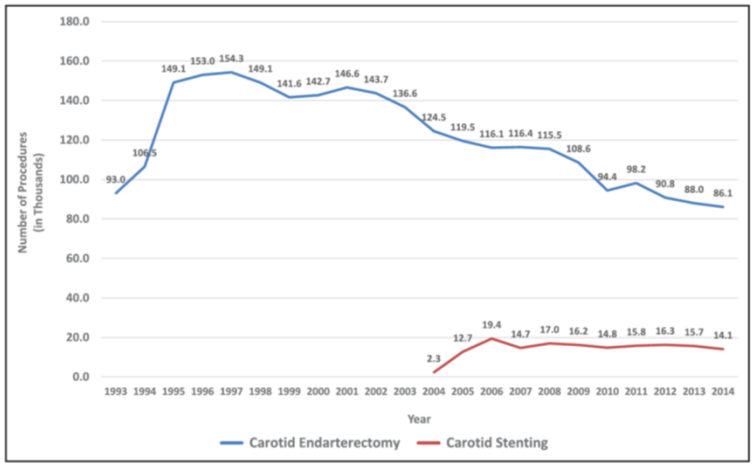


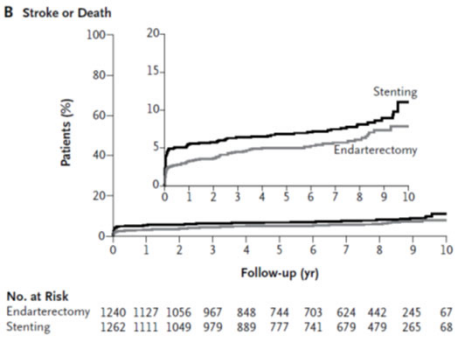
Chart 13-10. Trends in carotid endarterectomy and carotid stenting procedures (United States: 1993–2014).

March 2005 (CMS NCD)

- Not changed since then

Are Carotid Stent Durable?

Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis N Engl J Med 2016;374:1021-31.



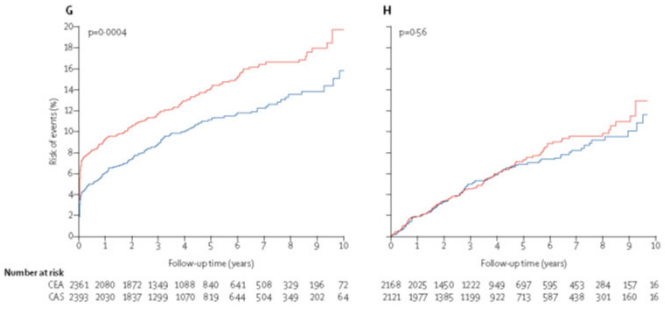
CREST (10 year data)

- No difference w/10 year "postprocedural" ipsilateral stroke rate
- Difference attributable to "periprocedural" risk (4.1% CAS vs 2.3% CEA)

Are Carotid Stent Durable?

Long-term outcomes of stenting and endarterectomy for symptomatic carotid stenosis: a preplanned pooled analysis of individual patient data

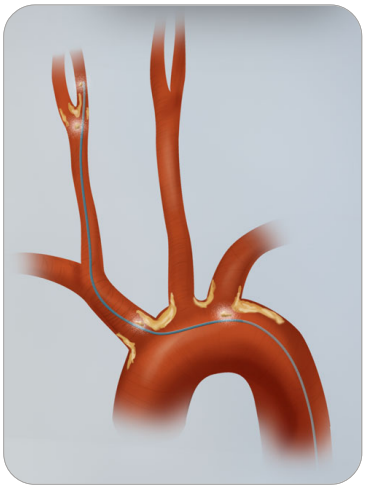
Lancet Neurol 2019; 18: 348–56



Pooled Analysis (10 year data)

- 4 largest RCT on CAS/CEA
- "improvement in periprocedural safety of CAS could provide similar outcomes")

Causes of Stroke During *TF*-CAS



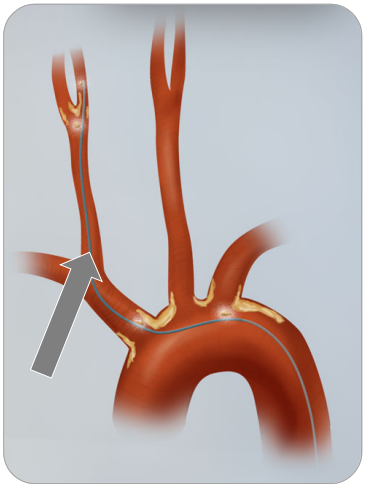
<u>Three Procedural Phases</u>

1. Catheterization
   - Passage of aortic arch
   - Catheterize target vessel
   - Introduction of sheath

2. "Unprotected" crossing of lesion
   - Placement of embolic protection device (EPD)

3. Intervention
   - Balloon angioplasty
   - Stent deployment
   - Recovery of EPD

Causes of Stroke During *TF*-CAS



Three Procedural Phases

1. Catheterization
   - Introduction of sheath

Transcarotid Filter Protected CAS

2. "Unprotected" crossing of lesion
   - Placement of embolic protection device (EPD)

3. Intervention
   - Balloon angioplasty
   - Stent deployment
   - Recovery of EPD

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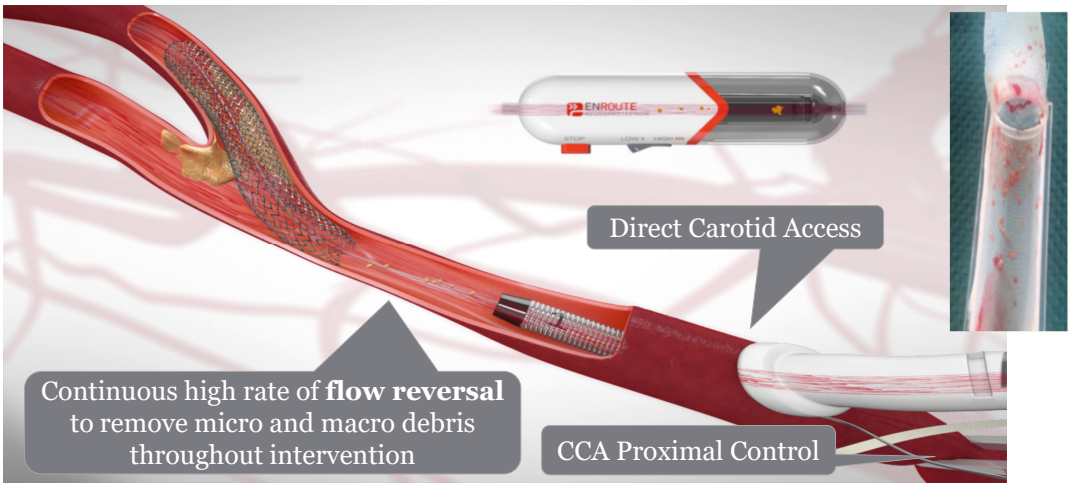
TransCarotid Artery Revascularization (TCAR)



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TransCarotid Artery Revascularization (TCAR)

Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal

(J Vasc Surg 2015;62:1227-35.)

- 141 "pivotal" patients in 18 sites
- 2012 to 2013
- 30 day all-stroke per protocol 0.7%

4.1%
TF-CAS (CREST)
Standard Surgical Risk

2.3%
CEA (CREST)
Standard Surgical Risk

1.4%
ROADSTER
High Surgical Risk

- "The overall **stroke rate** of **1.4%** is the **lowest reported to date** for any prospective, multi-center trial of carotid stenting." (FDA approval in 2015)

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TransCarotid Artery Revascularization (TCAR)

Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease

Stroke. 2020;51:2620–2629.

- FDA mandated post-approval TCAR registry
- 81.2% TCAR-naïve operators
- 692 "high risk" patients over 43 sites
- Analysis of 632 "per-protocol"
  - 4 strokes (0.6%); 1 death (0.2%), 6 MI (0.9%)
  - 30 day composite stroke/death/MI of 1.7%

0.6%
ROADSTER2
High Surgical Risk

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Current Practice Guidelines

Guidelines for the Primary Prevention of Stroke

A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association

(*Stroke*. 2014;45:3754-3832.)

- Prescribed daily aspirin and statin
- Reasonable to consider CEA in asymptomatic patients with >70% stenosis if risk of perioperative stroke/MI/death is low (<3%), however, its effectiveness compared to BMT is not well established
- Prophylactic CAS might be considered in highly selected patients, but its effectiveness compared to BMT is not well established
- In patients at high risk of complication by either CEA/CAS, effectiveness of revascularization versus medical therapy alone is not well established

How Many Strokes Can We Prevent???

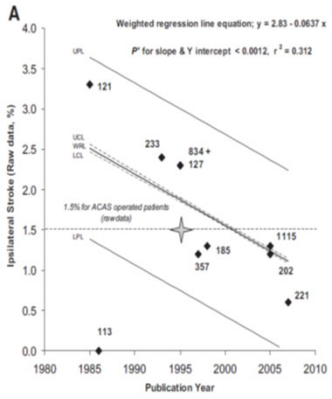
- Decreasing incidence of stroke (AHA, Circulation, 2020)
- Medical intervention is improving

Medical (Nonsurgical) Intervention Alone Is Now Best for Prevention of Stroke Associated With Asymptomatic Severe Carotid Stenosis

Results of a Systematic Review and Analysis

Anne L. Abbott, PhD, MBBS, FRACP

(*Stroke*. 2009;40:e573-e583.)



"Effectiveness" for CEA

- "real world data": efficacy vs effectiveness

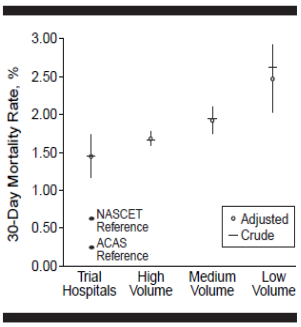
Variation in Carotid Endarterectomy Mortality in the Medicare Population

Trial Hospitals, Volume, and Patient Characteristics

David E. Wennberg, MD, MPH; F. L. Lucas, PhD; John D. Birkmeyer, MD; Carl E. Bredenberg, MD; Elliott S. Fisher, MD, MPH

JAMA. 1998;279:1278-1281

Conclusion.—Medicare patients' perioperative mortality following CEA is substantially higher than that reported in the trials, even in those institutions that participated in the randomized studies. Caution is advised in translating the efficacy of carefully controlled studies of CEA to effectiveness in everyday practice.



Crude and adjusted (controlling for age, sex, race, comorbidity, and urgency of admission) 30-day mortality rates following carotid endarterectomy. Crude (lines) and adjusted (open circles with 95% confidence intervals) perioperative mortality rates at trial and nontrial institutions are shown. As references, the perioperative mortality rates from the North American Symptomatic Carotid Endarterectomy Trial (NASCET) and the Asymptomatic Carotid Atherosclerosis Study (ACAS) are included.

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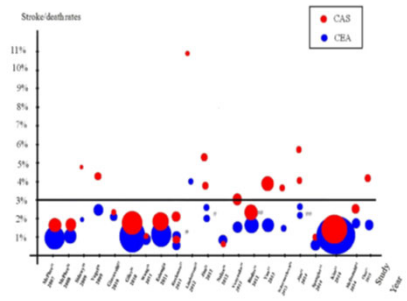
"Effectiveness" for CEA/CAS

Stroke/Death Rates Following Carotid Artery Stenting and Carotid Endarterectomy in Contemporary Administrative Dataset Registries: A Systematic Review

Eur J Vasc Endovasc Surg (2016) 51, 3–12



- Higher than 3% stroke/death for asymptomatic
  - 9 of 21 CAS studies
  - 1 of 21 CEA studies

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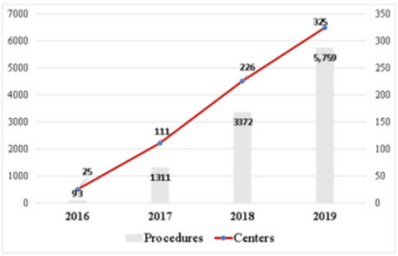
“Effectiveness” for TCAR

- National Coverage Decision for Carotid Stenting
  - Since 2005, symptomatic, high risk, ≥70%
- September 2016: SVS-PSO-VQI-TSP
  - “Real-world” outcome of TCAR vs CEA
  - Asymptomatic, high risk, ≥80% stenosis
  - Symptomatic, high risk, ≥50% stenosis
  - All data is collected



TCAR vs TF-CAS

JAMA | Original Investigation

Association of Transcarotid Artery Revascularization vs Transfemoral Carotid Artery Stenting With Stroke or Death Among Patients With Carotid Artery Stenosis JAMA. 2019;322(23):2313-2322.

- 9/16 to 4/19; 1035 physicians from 319 centers; 95.4% of all TCAR procedures
- 3282 propensity matched “pairs”
- TCAR: Vascular surgeons (85%), general surgeons (9%), neurosurgeon (2%), cardiologist (1%)
- TF-CAS: VS (28%), rad (21%), card (20%), NS (13%), neuro (11%), GS (3%)

TCAR vs TF-CAS

Table 2. In-Hospital Perioperative Outcomes After Transcarotid Artery Revascularization or Transfemoral Carotid Artery Stenting in a Propensity Score–Matched Study Population

Outcome	Transcarotid Artery Revascularization[a] (n = 3286)	Transfemoral Carotid Artery Stenting[a] (n = 3286)	Absolute Difference (95% CI), %	Relative Risk (95% CI)	*P* Value
Stroke or death	52 (1.6)	102 (3.1)	−1.52 (−2.29 to −0.75)	0.51 (0.37 to 0.72)	<.001
Stroke or death, 30 d	64 (1.9)	121 (3.7)	−1.73 (−2.57 to −0.90)	0.53 (0.39 to 0.72)	<.001
Stroke	43 (1.3)	79 (2.4)	−1.10 (−1.79 to −0.41)	0.54 (0.38 to 0.79)	.001
Stroke, 30 d	44 (1.3)	83 (2.5)	−1.19 (−1.89 to −0.49)	0.53 (0.37 to 0.76)	<.001
Transient ischemic attack	22 (0.7)	32 (1.0)	−0.30 (−0.77 to 0.16)	0.69 (0.40 to 1.18)	.17
Death	14 (0.4)	32 (1.0)	−0.55 (−0.98 to −0.11)	0.44 (0.23 to 0.82)	.008
Death, 30 d	25 (0.8)	48 (1.5)	−0.70 (−1.24 to −0.16)	0.52 (0.32 to 0.84)	.007
Myocardial infarction	7 (0.2)	10 (0.3)	−0.09 (−0.37 to 0.19)	0.70 (0.27 to 1.84)	.47

- Lower risk of in-hospital stroke or death, stroke, and death
- No difference in MI

41

TCAR vs CEA

OUTCOMES OF TRANSCAROTID REVASCULARIZATION WITH DYNAMIC FLOW REVERSAL (TCAR) VERSUS CAROTID ENDARTERECTOMY (CEA) IN THE TCAR SURVEILLANCE PROJECT

Presented at SVS VAM 2019

- 9/16 to 5/19: 5719 TCAR (236 centers) and 44442 CEA (354 centers)
- TCAR: older, more symptomatic, more comorbidities, more likely redo-carotid intervention/CEA

42

TCAR vs CEA

Propensity Score and Coarsened-Exact Matching

	Propensity Score Matching (n=5,160 in each)		1:1 CEM (n=4,895 in each)	
	OR (95% CI)	*P-value*	*OR (95% CI)*	*P-value*
In-Hospital Outcomes				
Death	0.86 (0.46-1.61)	0.63	0.89 (0.50-1.60)	0.70
Ipsilateral Stroke	0.92 (0.64-1.32)	0.64	0.97 (0.71-1.33)	0.85
Stroke	0.80 (0.58-1.11)	0.19	0.85 (0.63-1.13)	0.27
MI	0.41 (0.26-0.66)	**<0.001**	0.46 (0.30-0.71)	**<0.001**
Stroke/Death	0.77 (0.57-1.04)	0.09	0.84 (0.64-1.10)	0.20
Stroke/Death/MI	0.65 (0.50-0.84)	**<0.01**	0.69 (0.55-0.87)	**<0.01**
Cranial Nerve Injury	0.13 (0.07-0.22)	**<0.001**	0.12 (0.07-0.21)	**<0.001**
Post-procedural Hypotension	1.66 (1.47-1.87)	**<0.001**	1.63 (1.49-1.78)	**<0.001**
Post-procedural Hypertension	0.64 (0.57-0.71)	**<0.001**	0.57 (0.51-0.63)	**<0.001**
Bleeding with intervention	1.17 (0.83-1.65)	0.38	1.14 (0.87-1.50)	0.33
Non-Home discharge	0.75 (0.64-0.87)	**<0.001**	0.76 (0.67-0.86)	**<0.001**
Hospital Stay for more than 1 day	0.74 (0.68-0.80)	**<0.001**	0.73 (0.67-0.79)	**<0.001**

Matched on symptomatic status, age, CAD, CHF, COPD, CKD, prior ipsilateral CEA, prior ipsilateral CAS, contralateral occlusion, ASA Class and statin use

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TCAR Learning Curve

Learning Curve for Surgeons Adopting Transcarotid Artery Revascularization Based on the Vascular Quality Initiative-Transcarotid Artery Revascularization Surveillance Project

Check for updates

(J Am Coll Surg 2020;230:113–120.

Category	Cases	Operators
Novice (1-5)	1426 (41%)	196 (47%)
Intermediate (6-20)	1375 (40%)	159 (38%)
Advanced (20-30)	307 (8.9%)	44 (11%)
Expert (>30)	348 (10%)	18 (4%)

- No differences in stroke/mortality
- Increasing experience associated w/improved efficiency, more complex patients, less use of general anesthesia
- Expert level had no failures

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Optimize TCAR Effectiveness

Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease

Stroke. 2020;51:2620–2629.

- 692 "high risk" patients over 43 sites
- Analysis of 60 "protocol violations"
  - 11 inclusion/exclusion criteria; remainder had **medication noncompliance**
  - 9 more strokes; 11 stroke/death; no change in MI

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Who Will I Treat in 2021???

- **Symptomatic** patients (**≥70%** and **select ≥50%**)

- **Asymptomatic** patients
  - Good surgical candidate (active/functioning, comorbidities well controlled)
  - **3-5 year** life expectancy
  - Carotid stenosis **≥80%** (EDV >140, CTA)
  - Perioperative mortality/morbidity **<1%**

- "TCAR first" in high risk patients…but only with appropriate anatomy
- Otherwise CEA, rare situation require *TF*-CAS

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Anything Else We Should Know?

The Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Study

Health and Hope for Patients at Risk for Stroke

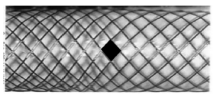
- Started in 2014
- Two parallel multi-center RCT
  - Aggressive medical management vs CEA
  - Aggressive medical management vs CAS (TCAR)
  - >70% asymptomatic patients (2480 participants; 40% women; 12% minorities)

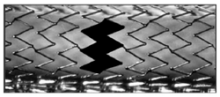
Anything Else We Should Know?

- Identification of "high risk" patients with carotid stenosis
  - Sub-stratify lesions, overall cranial perfusion, cognitive effects
  - Ultrasound: plaque evaluation (thrombus)
  - CT/MRI: plaque characteristics/silent embolic infarcts
  - PET: inflammatory markers/plaque stability
  - Transcranial Doppler (TCD)
    - Microembolic signal
    - Velocity/flow measurement

Anything Else We Should Know?

- Improvement in Stent Design





Stent Name	Stent Image	Stent Design	Free Cell Area	Specifics of Design	Stent Diameter (unconstrained)	Stent Length (unconstrained)
Gore		Mesh Covered	0.5mm2	PTFE mesh (heparin coated) on nitinol stent)	unable to obtain specifics	
Roadsaver		Mesh Covered	0.4mm2	Nitinol double layer micromesh	5 - 10mm (15 - 30Fr)	25 - 43mm
InspireMD Cguard		Mesh Covered	0.18mm 2	PET MicroNet on nitinol stent	6 - 10mm (18 - 30Fr)	20 - 60mm

Richards CN, et al. Sem Vasc Surg 2017;30:25-30

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Anything Else We Should Know?

A First-in-Human Evaluation of a Novel Mesh-Covered Stent for Treatment of Carotid Stenosis in Patients at High Risk for Endarterectomy
30-Day Results of the SCAFFOLD Trial
JACC: CARDIOVASCULAR INTERVENTIONS VOL. 11, NO. 23, 2018

Clinical trial of carotid artery stenting using dual-layer CASPER stent for carotid endarterectomy in patients at high and normal risk in the Japanese population
J NeuroIntervent Surg 2020

Use of Dual-Layered Stents in Endovascular Treatment of Extracranial Stenosis of the Internal Carotid Artery
Results of a Patient-Based Meta-Analysis of 4 Clinical Studies
JACC: CARDIOVASCULAR INTERVENTIONS VOL. 11, NO. 23, 2018

Reduction of cerebral DWI lesion burden after carotid artery stenting using the CASPER stent system
J NeuroIntervent Surg 2019;

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Summary/Conclusion

- Stroke and carotid artery stenosis remain significant disease processes
- Optimal medical management is mandatory for all patients with carotid stenosis
- There appears to be potential benefit in appropriate screening in otherwise asymptomatic patients
- Carotid revascularization remains an important treatment option for select patients
  - Optimal approach (TCAR vs CEA) dependent on patient anatomy
- Future research will further identify “high risk” asymptomatic patients and continue to reduce risks associated with carotid revascularization

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