Carotid Revascularization Procedures:

The Rise of TCAR

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Michigan Vascular Society: May 17, 2023

Disclosures

- Related: Silk Road Medical
- Unrelated: W.L. Gore, Cook Medical
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  - American College of Surgeons
  - NIH/NIDDK
  - Society for Vascular Surgery

Cerebrovascular Disease

2^{nd} leading cause of death

15% severely disabling

$70 billion annually

Evolution of Carotid Revasc

1990s

1ST Successful CEA performed in **1953** Dr. Michael DeBakey

Heart and Vascular Institute

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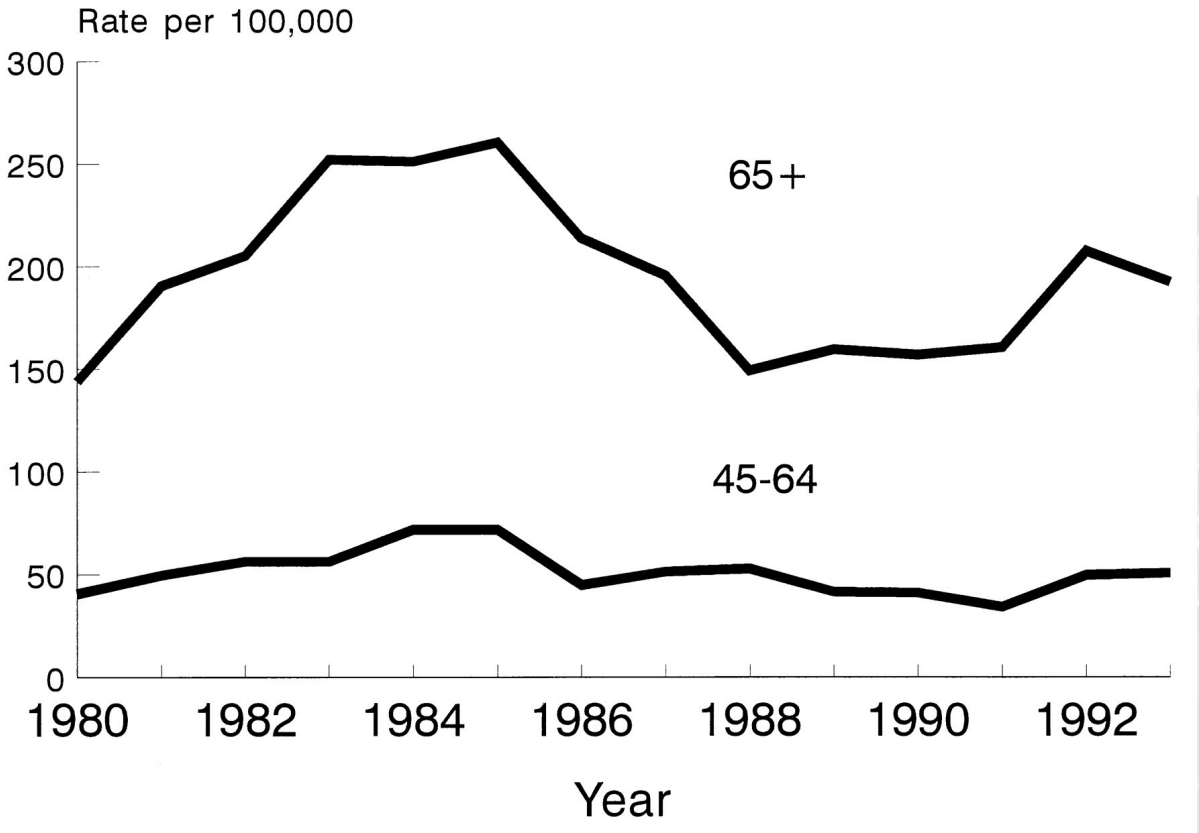
Adoption of Carotid Endarterectomy



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Gillum et al. Stroke. 1995 Sep;26(9):1724-8.

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Randomized Controlled Trials
CEA vs. Medical Management

- Symptomatic
  - North American Symptomatic Carotid Endarterectomy Trial (NASCET)
  - European Carotid Surgery Trial (ECST)

- Asymptomatic
  - Asymptomatic Carotid Atherosclerosis Trial (ACAS)
  - Asymptomatic Carotid Surgery Trial (ACST)

Randomized Trials - Symptomatic
CEA vs. Medical Management

	Indication	Periop CVA/Death	Risk Reduction	Annual Risk Reduction	P Value
NASCET	Sx ≥ 70%	5.8%	16.5% @ 2yr	8%	<0.001
	Sx 50-69%	6.7%	10.1% @ 5yr	2%	<0.05
ECST	Sx 70-99%	7.5%	9.6% @ 5yr	2%	<0.01

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Ferguson et al. Stroke 1999 Sep;30(9):1751-8.
Lancet 1998 May 9;351(9113):1379-8

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Randomized Trials - Asymptomatic
CEA vs. Medical Management

	Indication	Periop CVA/Death	Risk Reduction	Annual Risk Reduction	P Value
ACAS	Asx >60%	2.3	5.9% @ 5yr	1%	0.004
ACST	Asx >60%	3.1	5.4% @ 5yr	1%	<0.001

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JAMA 1995 May 10;273(18):1421-8
Haliday et al. Lancet 2004 May 8;363(9420):1491-502

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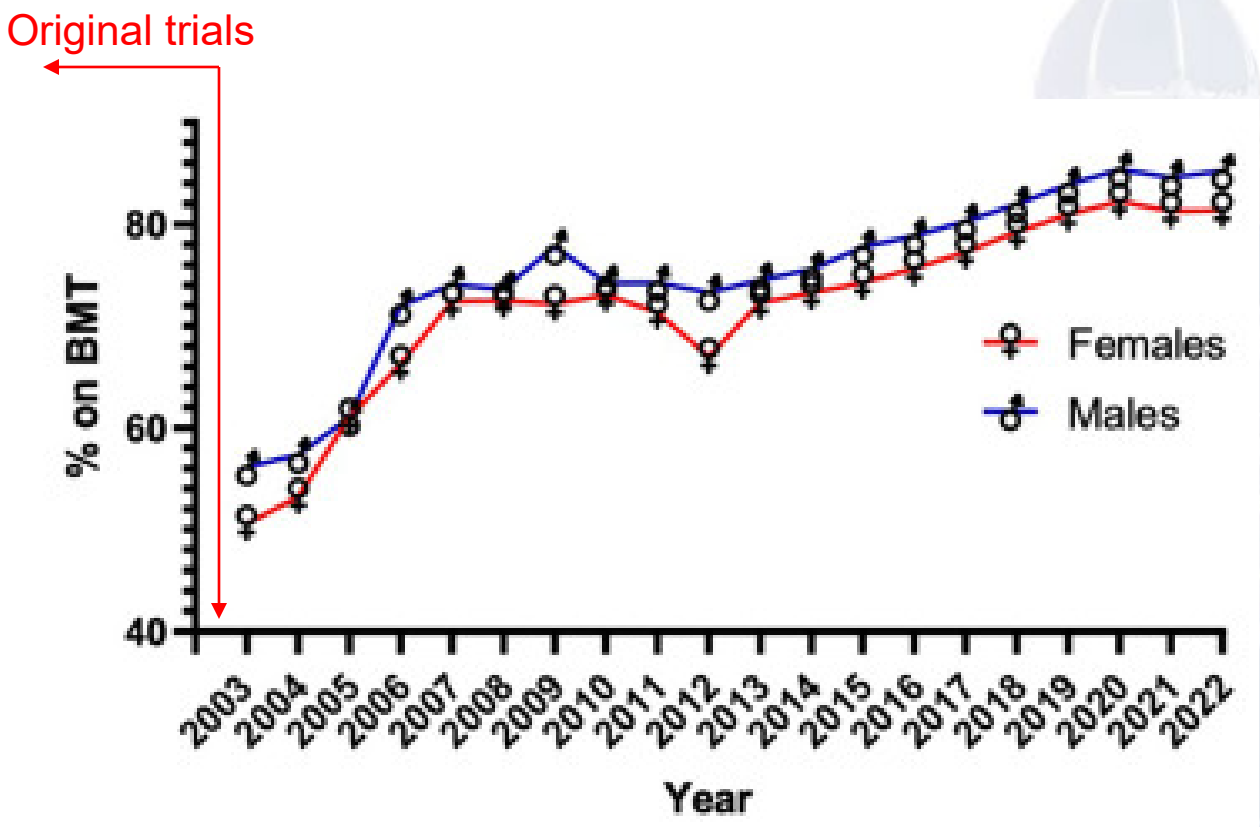
Randomized Trials
CEA vs. Medical Management

- Complications
  - Death
  - Stroke
  - Myocardial infarction
  - Cranial nerve injury
    - Occur in 5-20%
    - 1/3 of deficits are asymptomatic
    - Permanent in 0.5-1%

Medical Management has Changed



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Bose et al. J Vasc Surg. 2023 Mar;77(3):786-794.e2

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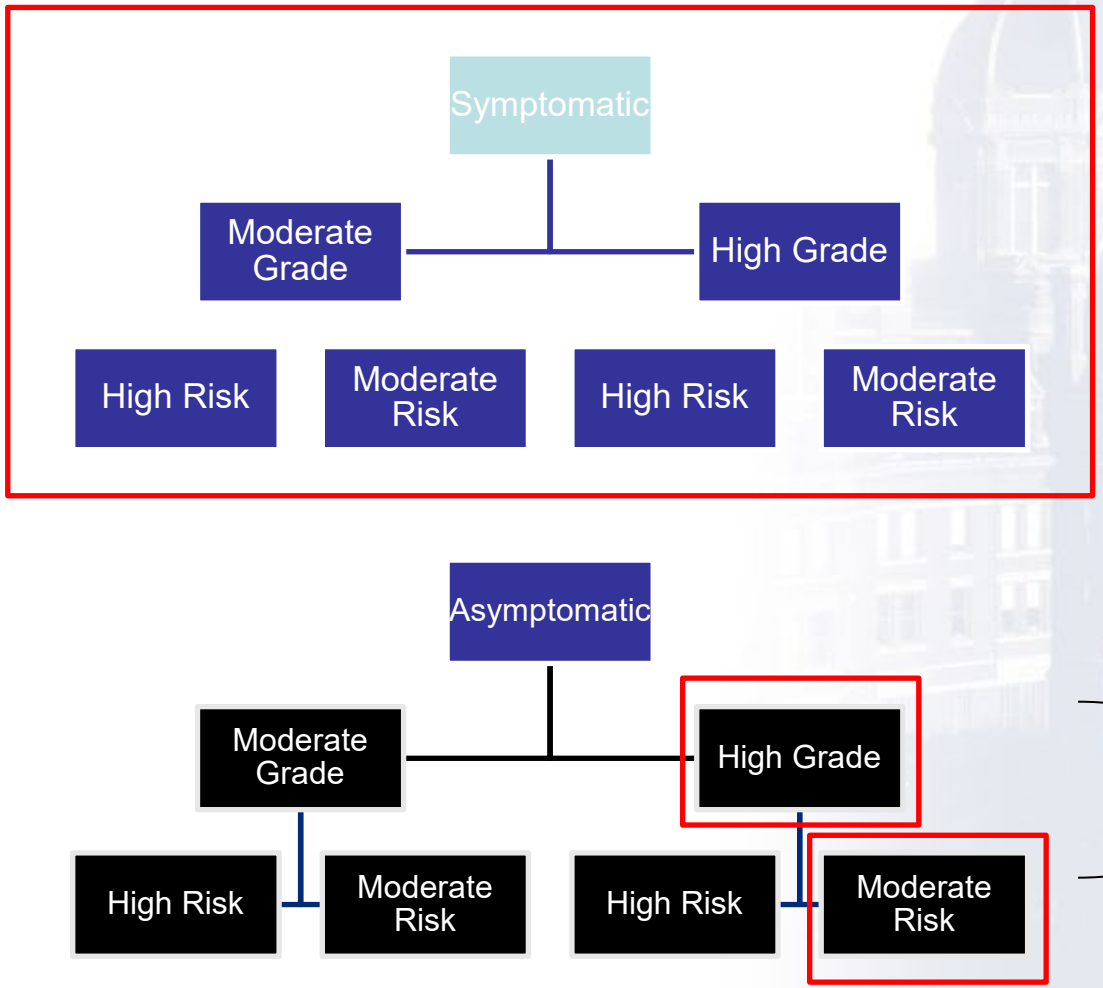
When To Operate



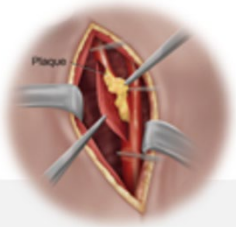
CREST II

- Randomized 2 arm study
  - Med Tx vs. CEA
  - Med Tx vs. TF-CAS
- Must be asymptomatic, >70% stenosis
- Primary endpoint
  - Any stroke/death during periprocedural period
  - Any stroke during 4 year f/u

➢ Meant to redefine therapy for asymptomatic disease

CEA arm enrollment nearly complete

Evolution of Carotid Revasc



1ST Successful CEA performed in **1953** Dr. Michael DeBakey

1990s

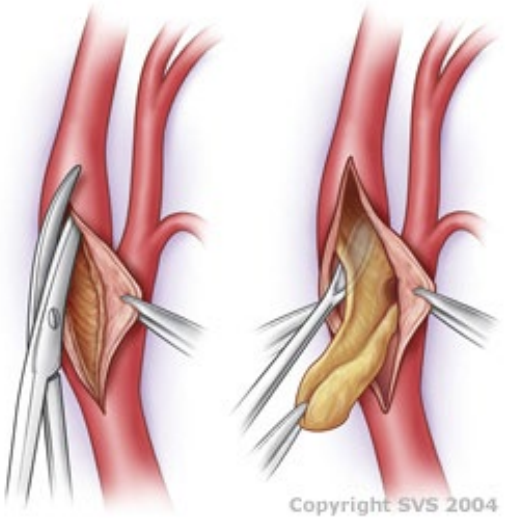
Trans Femoral Carotid Stenting

From 1994

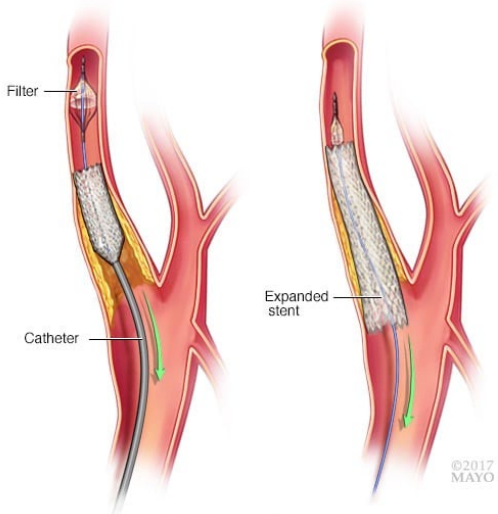
- CREST
- SAPPHIRE

Carotid Revascularization

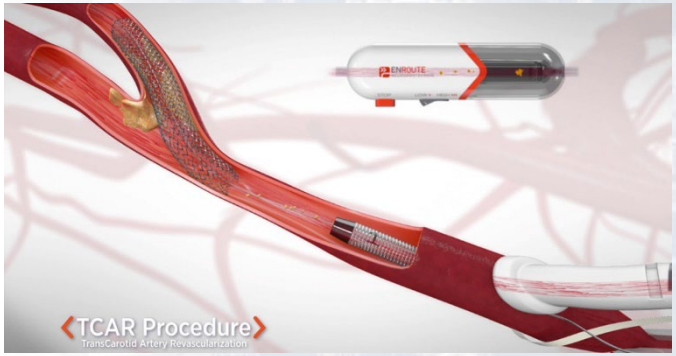
Carotid Endarterectomy (CEA)



Transfemoral Carotid Stenting (TFCAS)



TransCarotid Artery Revascularization (TCAR)



Randomized Trials
CEA vs. TF-CAS

- EVA-3S
  - Std R
- SPACE
  - Std R
- ICSS
  - Std R
- CREST
  - Std R
- Sapphire
  - High Risk: Sx >50%, Asx >80% with EPD

Variation

1. Indication
2. Risk
3. Embolic Protection Device
4. Outcomes

ICSS - Symptomatic

Randomized Controlled Trial > Lancet. 2015 Feb 7;385(9967):529-38.
doi: 10.1016/S0140-6736(14)61184-3. Epub 2014 Oct 14.

Long-term outcomes after stenting versus endarterectomy for treatment of symptomatic carotid stenosis: the International Carotid Stenting Study (ICSS) randomised trial

Leo H Bonati [1], Joanna Dobson [2], Roland L Featherstone [3], Jörg Ederle [3], H Bart van der Worp [4], Gert J de Borst [5], Willem P Th M Mali [6], Jonathan D Beard [7], Trevor Cleveland [7], Stefan T Engelter [8], Philippe A Lyrer [8], Gary A Ford [9], Paul J Dorman [10], Martin M Brown [11], International Carotid Stenting Study investigators

- Symptomatic stenosis ≥50%
- Life expectancy >2 years

ICSS - Symptomatic

	Stenting (n=853)			Endarterectomy (n=857)			Hazard ratio* (95% CI)	Absolute risk difference (95% CI)	
	Number of events*	Cumulative 1-year risk (SE)†	Cumulative 5-year risk (SE)†	Number of events*	Cumulative 1-year risk (SE)†	Cumulative 5-year risk (SE)†		At 1 year	At 5 years
Fatal or disabling stroke (primary outcome measure)	52	3·9% (0·7)	6·4% (0·9)	49	3·2% (0·6)	6·5% (1·0)	1·06 (0·72 to 1·57)	0·7% (−1·0 to 2·5)	−0·2% (−2·8 to 2·5)
Any stroke	119	9·5% (1·0)	15·2% (1·4)	72	5·1% (0·8)	9·4% (1·1)	1·71 (1·28 to 2·30)‡	4·4% (1·9 to 6·9)	5·8% (2·4 to 9·3)
Procedural stroke or procedural death or ipsilateral stroke during follow-up	95	9·0% (1·0)	11·8% (1·2)	57	4·7% (0·7)	7·2% (0·9)	1·72 (1·24 to 2·39)§	4·2% (1·9 to 6·6)	4·6% (1·6 to 7·6)
All-cause death	153	4·9% (0·7)	17·4% (1·5)	129	2·3% (0·5)	17·2% (1·5)	1·17 (0·92 to 1·48)	2·6% (0·8 to 4·4)	0·2% (−4·0 to 4·4)

*Calculated as the first relevant event between randomisation and the end of follow-up. †Calculated from randomisation onwards. ‡p<0·001. §p<0·01.

Table 2: **Intention-to-treat analysis of cumulative risks and hazard ratios of main outcome events**

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Bonati LH et al. Lancet. 2015 Feb 7;385(9967):529-38.

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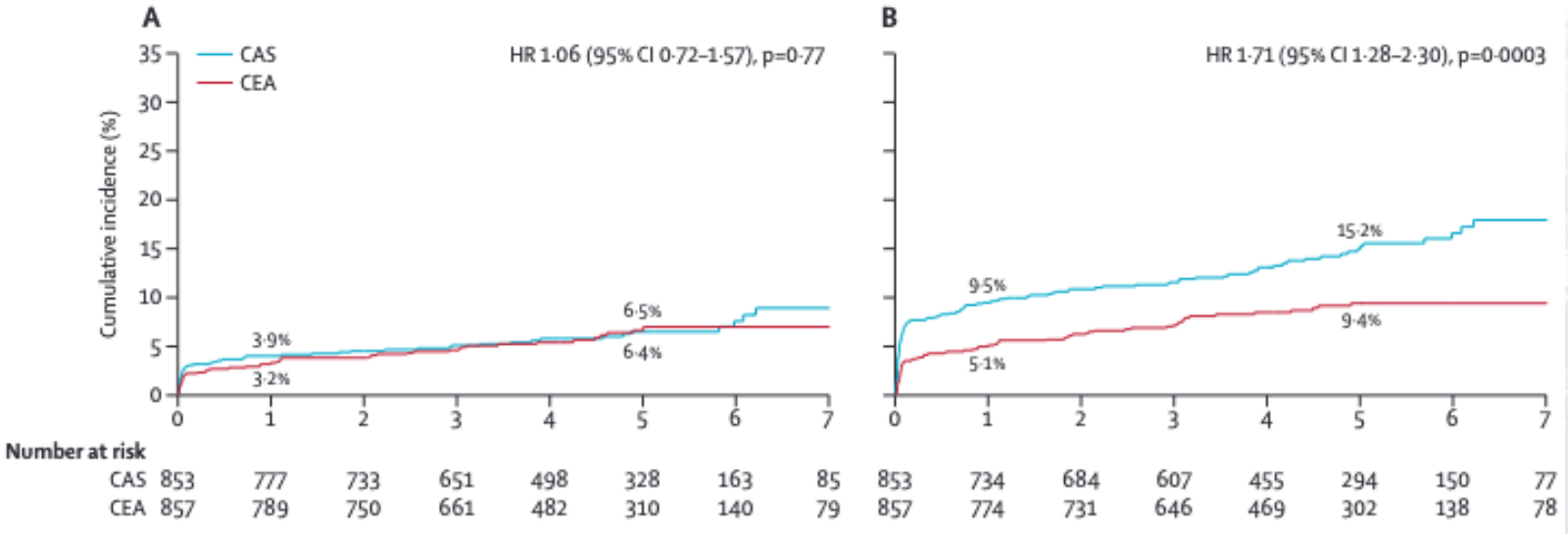
ICSS - Symptomatic

Fatal/disabling stroke

Any stroke



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CREST

Randomized Controlled Trial > N Engl J Med. 2010 Jul 1;363(1):11-23.
doi: 10.1056/NEJMoa0912321. Epub 2010 May 26.

Stenting versus endarterectomy for treatment of carotid-artery stenosis

Thomas G Brott [1], Robert W Hobson 2nd, George Howard, Gary S Roubin, Wayne M Clark, William Brooks, Ariane Mackey, Michael D Hill, Pierre P Leimgruber, Alice J Sheffet, Virginia J Howard, Wesley S Moore, Jenifer H Voeks, L Nelson Hopkins, Donald E Cutlip, David J Cohen, Jeffrey J Popma, Robert D Ferguson, Stanley N Cohen, Joseph L Blackshear, Frank L Silver, J P Mohr, Brajesh K Lal, James F Meschia, CREST Investigators

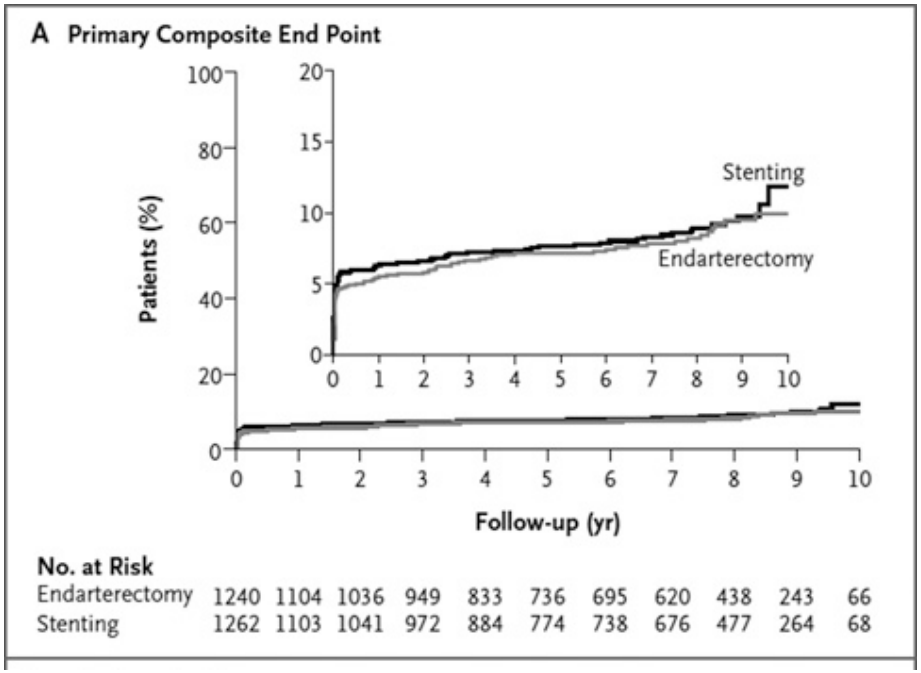
- Symptomatic patients with stenosis ≥50%
- Asymptomatic patients with stenosis ≥60%
- Surgeons performed >12 procedures per year & complications/death <3% among asymptomatic patients and <5% among symptomatic patients

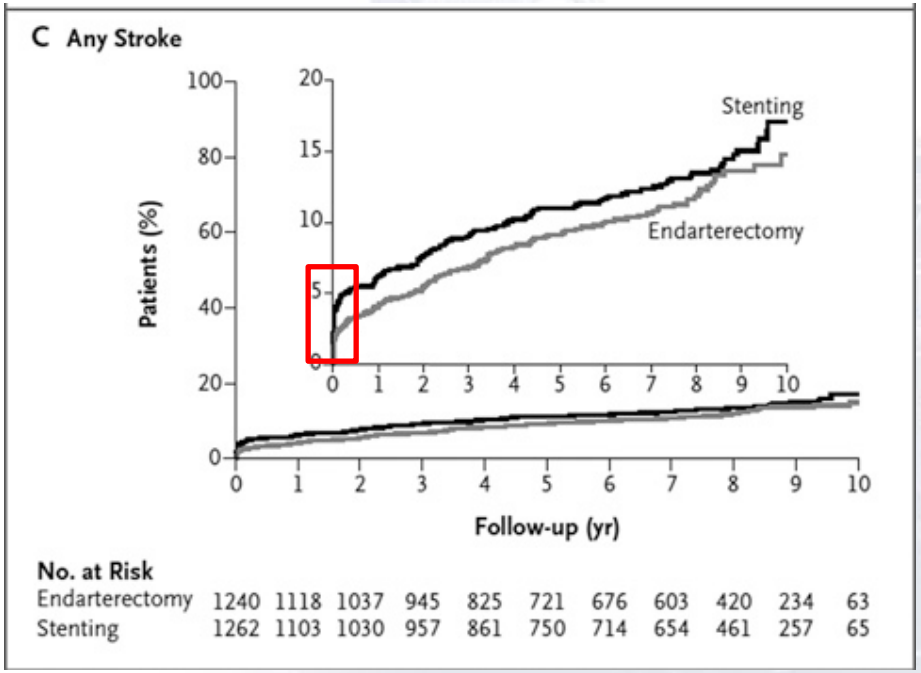
CREST

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 postprocedural 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

Brott et al. N Engl J Med. 2010 Jul 1;363(1):11-23.

CREST





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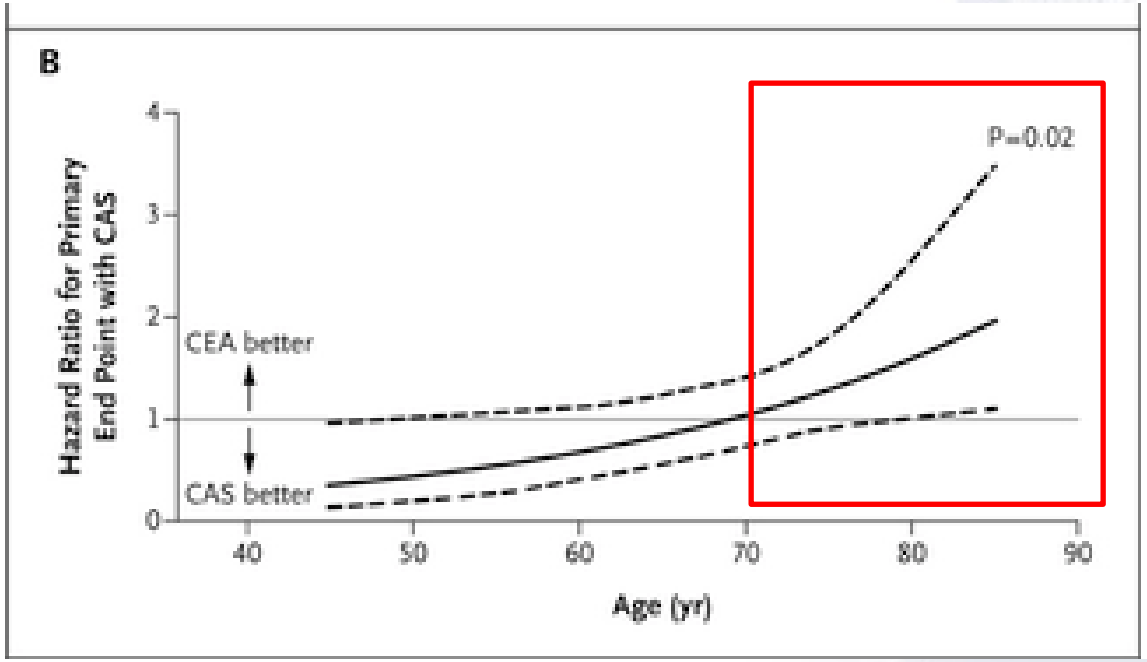
Brott et al. N Engl J Med. 2016 Mar 17; 374(11): 1021–1031.

CREST – Age Interaction



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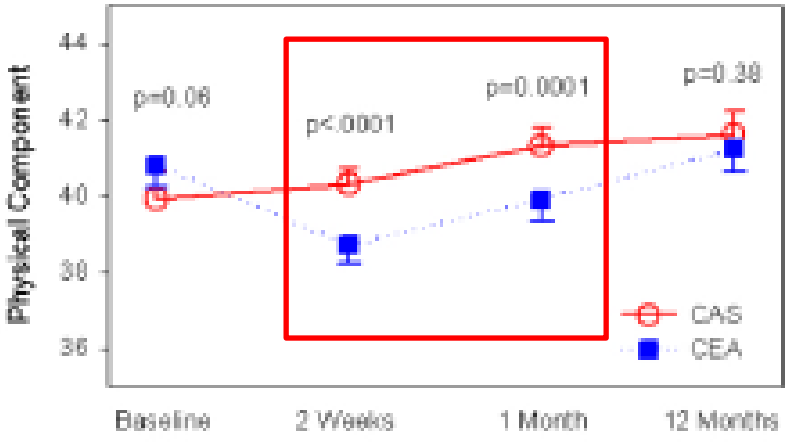
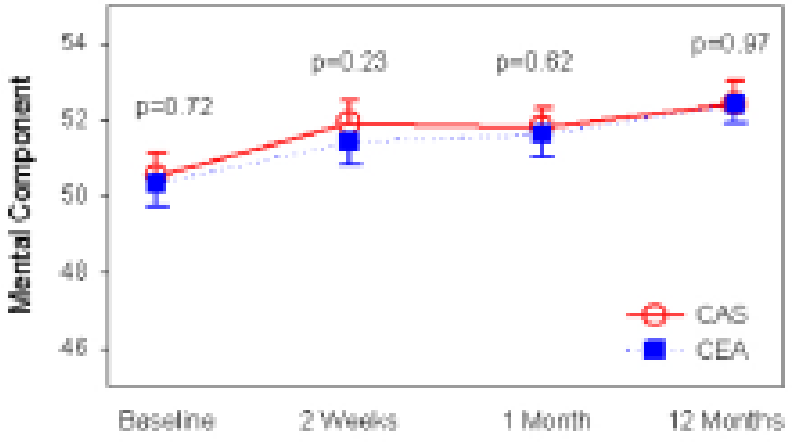
Brott et al. N Engl J Med. 2010 Jul 1;363(1):11-23.

CREST - HRQOL

Health-Related Quality of Life after Carotid Stenting versus Carotid Endarterectomy: Results from CREST (Carotid Revascularization Endarterectomy Versus Stenting Trial)

David J. Cohen, MD, MSc[1], Joshua M. Stolker, MD[2], Kaijun Wang, PhD[1], Elizabeth A. Magnuson, ScD[1], Wayne M. Clark, MD[3], Bart M. Demaerschalk, MD, MSc[4], Albert D. Sam II, MD[5], James R. Elmore, MD[6], Fred A. Weaver, MD, MMM[7], Herbert D. Aronow, MD, MPH[8], Larry B. Goldstein, MD[9], Gary S. Roubin, MD, PhD[10], George Howard, DrPH[11], and Thomas G. Brott, MD[12] on behalf of the CREST Investigators





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J Am Coll Cardiol. 2011 October 4; 58(15): 1557–1565.

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SAPPHIRE – High Risk

Clinical Trial > N Engl J Med. 2004 Oct 7;351(15):1493-501. doi: 10.1056/NEJMoa040127.

Protected carotid-artery stenting versus endarterectomy in high-risk patients

Jay S Yadav [1], Mark H Wholey, Richard E Kuntz, Pierre Fayad, Barry T Katzen, Gregory J Mishkel, Tanvir K Bajwa, Patrick Whitlow, Neil E Strickman, Michael R Jaff, Jeffrey J Popma, David B Snead, Donald E Cutlip, Brian G Firth, Kenneth Ouriel,
Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy Investigators

Table 1. Major Eligibility Criteria.

Inclusion criteria

General criteria
- Age ≥18 yr
- Unilateral or bilateral atherosclerotic or restenotic lesions in native carotid arteries
- Symptoms plus stenosis of more than 50 percent of the luminal diameter
- No symptoms plus stenosis of more than 80 percent of the luminal diameter

Criteria for high risk (at least one factor required)
- Clinically significant cardiac disease (congestive heart failure, abnormal stress test, or need for open-heart surgery)
- Severe pulmonary disease
- Contralateral carotid occlusion
- Contralateral laryngeal-nerve palsy
- Previous radical neck surgery or radiation therapy to the neck
- Recurrent stenosis after endarterectomy
- Age >80 yr

Exclusion criteria
- Ischemic stroke within previous 48 hr
- Presence of intraluminal thrombus
- Total occlusion of target vessel
- Vascular disease precluding use of catheter-based techniques
- Intracranial aneurysm >9 mm in diameter
- Need for more than two stents
- History of bleeding disorder
- Percutaneous or surgical intervention planned within next 30 days
- Life expectancy <1 yr
- Ostial lesion of common carotid artery or brachiocephalic artery

SAPPHIRE – High Risk

Table 4. Cumulative Incidence of Adverse Events at 30 Days.*

Event	Intention-to-Treat Analysis			Actual Treatment Analysis		
	Stent (N=167)	Endarterectomy (N=167)	P Value	Stent (N=159)	Endarterectomy (N=151)	P Value
	no. (%)			*no. (%)*		
Death	2 (1.2)	4 (2.5)	0.39	1 (0.6)	3 (2.0)	0.29
Stroke	6 (3.6)	5 (3.1)	0.77	5 (3.1)	5 (3.3)	0.94
Major ipsilateral	1 (0.6)	2 (1.2)	0.55	0	2 (1.3)	0.15
Major nonipsilateral	1 (0.6)	1 (0.6)	1.00	1 (0.6)	1 (0.7)	0.97
Minor ipsilateral	4 (2.4)	1 (0.6)	0.18	4 (2.5)	1 (0.7)	0.20
Minor nonipsilateral	1 (0.6)	1 (0.6)	1.00	1 (0.6)	1 (0.7)	0.97
Myocardial infarction	4 (2.4)	10 (6.1)	0.10	3 (1.9)	10 (6.6)	0.04
Q-wave	0	2 (1.2)	0.15	0	2 (1.3)	0.15
Non–Q-wave	4 (2.4)	8 (4.9)	0.23	3 (1.9)	8 (5.3)	0.11
Death, stroke, or myocardial infarction	8 (4.8)	16 (9.8)	0.09	7 (4.4)	15 (9.9)	0.06
Major vascular complications	2 (1.2)	1 (0.6)	0.57	2 (1.3)	1 (0.7)	0.60

Yadav JS et al. N Engl J Med. 2004 Oct 7;351(15):1493-501

SAPPHIRE – High Risk

Table 3. Cumulative Incidence of Adverse Events within One Year.*

Event	Intention-to-Treat Analysis			Actual-Treatment Analysis		
	Stenting (N=167)	Endarterectomy (N=167)	P Value	Stenting (N=159)	Endarterectomy (N=151)	P Value
	no. (%)			*no. (%)*		
Death	12 (7.4)	21 (13.5)	0.08	11 (7.0)	19 (12.9)	0.08
Stroke	10 (6.2)	12 (7.9)	0.60	9 (5.8)	11 (7.7)	0.52
Major ipsilateral	1 (0.6)	5 (3.3)	0.09	0	5 (3.5)	0.02
Major nonipsilateral	1 (0.6)	2 (1.4)	0.53	1 (0.6)	1 (0.7)	0.97
Minor ipsilateral	6 (3.7)	3 (2.0)	0.34	6 (3.8)	3 (2.2)	0.37
Minor nonipsilateral	3 (1.9)	4 (2.7)	0.64	3 (2.0)	3 (2.1)	0.89
Myocardial infarction	5 (3.0)	12 (7.5)	0.07	4 (2.5)	12 (8.1)	0.03
Q-wave	0	2 (1.2)	0.15	0	2 (1.3)	0.15
Non–Q-wave	5 (3.0)	10 (6.2)	0.17	4 (2.5)	10 (6.7)	0.08
Cranial-nerve palsy	0	8 (4.9)	0.004	0	8 (5.3)	0.003
Target-vessel revascularization	1 (0.6)	6 (4.3)	0.04	1 (0.7)	6 (4.6)	0.04
Conventional end point (stroke or death at 30 days plus ipsilateral stroke or death from neurologic causes within 31 days to 1 yr)	9 (5.5)	13 (8.4)	0.36	8 (5.1)	11 (7.5)	0.40
Primary end point (death, stroke, or myocardial infarction at 30 days plus ipsilateral stroke or death from neurologic causes within 31 days to 1 yr)	20 (12.2)	32 (20.1)	0.05	19 (12.0)	30 (20.1)	0.05

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Yadav JS et al. N Engl J Med. 2004 Oct 7;351(15):1493-501

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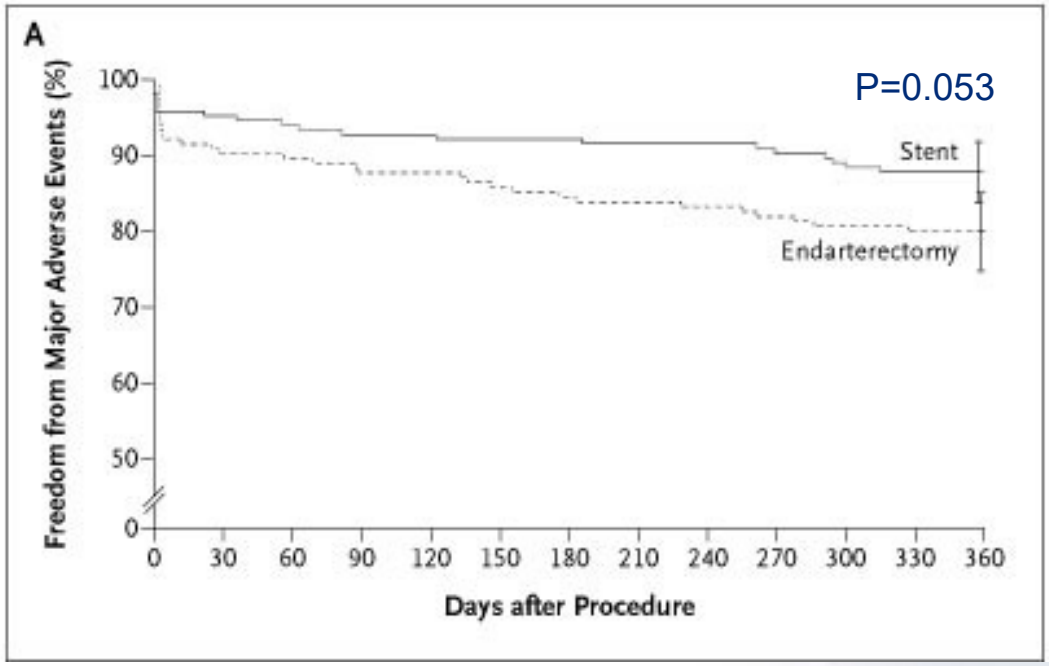
SAPPHIRE – High Risk



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Current CMS Coverage for TFCAS

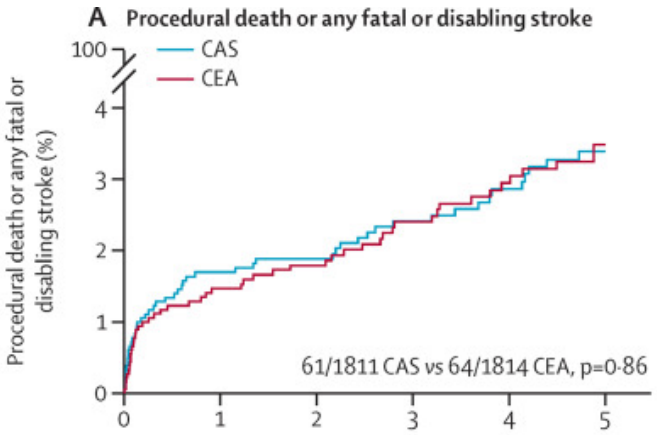
ONE risk factor qualifies patient for CMS high surgical risk status

- **Prior head/neck surgery or irradiation**
- **Restenosis post CEA**
- **Contralateral occlusion**
- **Surgically inaccessible lesion**
- **Severe tandem lesions**
- Bilateral stenosis requiring treatment
- Cervical spine immobility
- Uncontrolled diabetes
- LVEF <30%
- Chronic renal insufficiency (Creatinine ≥2.5 mg/dl)
- Need for open heart surgery
- MI >72hr & <6 weeks prior to procedure
- Permanent contralateral cranial nerve injury
- Severe pulmonary disease
- >2 diseased coronaries with ≥70% stenosis
- CHF with NYHA Class III or IV
- Need for major surgery (including vascular)
- Unstable angina
- Abnormal stress test
- Laryngeal palsy or laryngectomy

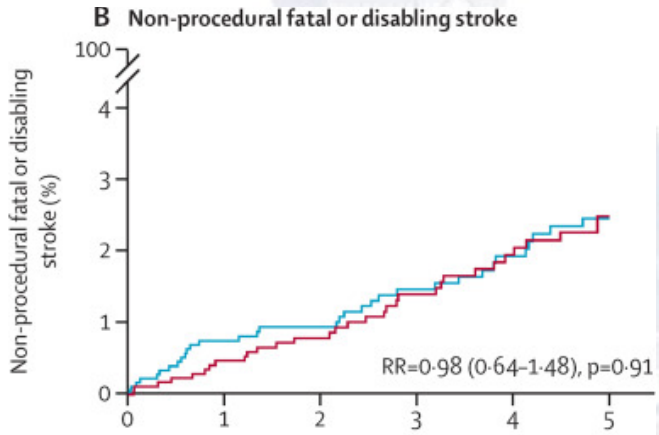
1. HSR, Symptomatic >50% stenosis
2. HSR, Asymptomatic ≥80% stenosis

NIHR HTA/BUPA Foundation/University of Oxford

Asymptomatic Carotid Surgery Trial (ACST-2)



Number at risk (number of events, annual rate [%])*						
CAS	1811	1639	1408	1186	993	789
	(30, 1·8%)	(3, 0·2%)	(7, 0·5%)	(5, 0·5%)	(5, 0·6%)	(11, 0·5%)
CEA	1814	1625	1422	1196	988	814
	(26, 1·5%)	(5, 0·3%)	(8, 0·6%)	(6, 0·6%)	(5, 0·6%)	(14, 0·6%)



Number at risk (number of events, annual rate [%])*						
CAS	1811	1639	1408	1186	993	789
	(13, 0·8%)	(3, 0·2%)	(7, 0·5%)	(5, 0·5%)	(5, 0·6%)	(11, 0·5%)
CEA	1814	1625	1422	1196	988	814
	(8, 0·5%)	(5, 0·3%)	(8, 0·6%)	(6, 0·6%)	(5, 0·6%)	(13, 0·6%)

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Halliday et al. 2021 Sep 18;398(10305):1065-1073

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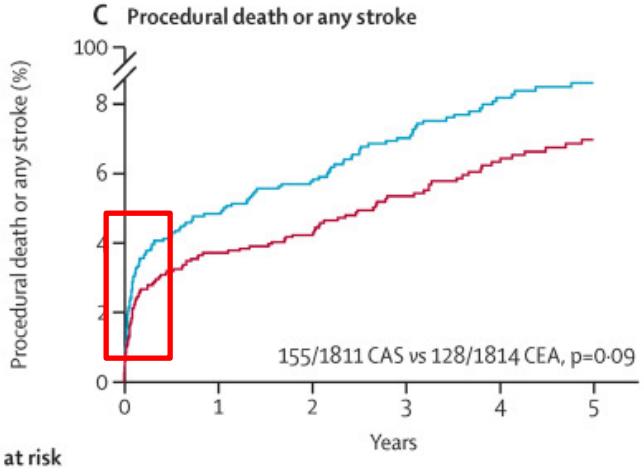
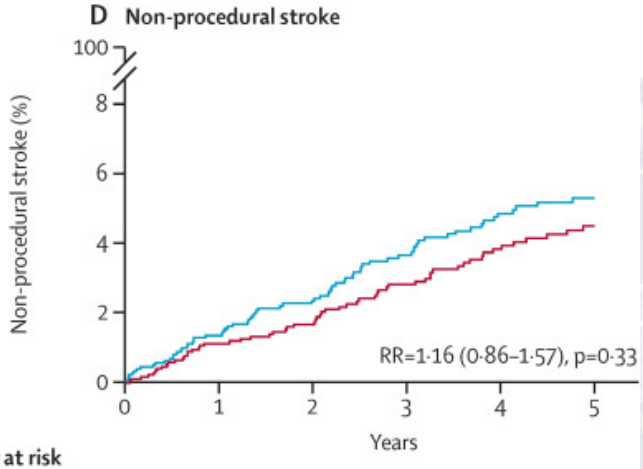
NIHR HTA/BUPA Foundation/University of Oxford

Asymptomatic Carotid Surgery Trial (ACST-2)



Number at risk (number of events, annual rate [%])*

CAS	1811	1588	1353	1131	935	741
	(86, 5·2%)	(15, 1·0%)	(17, 1·4%)	(13, 1·3%)	(4, 0·5%)	(20, 1·0%)
CEA	1814	1587	1386	1156	946	775
	(66, 4·0%)	(8, 0·5%)	(15, 1·2%)	(11, 1·1%)	(6, 0·7%)	(22, 1·1%)



Number at risk (number of events, annual rate [%])*

CAS	1811	1588	1353	1131	935	741
	(23, 1·4%)	(15, 1·0%)	(17, 1·4%)	(13, 1·3%)	(4, 0·5%)	(19, 0·9%)
CEA	1814	1587	1386	1156	946	775
	(19, 1·1%)	(8, 0·5%)	(15, 1·2%)	(11, 1·1%)	(6, 0·7%)	(20, 1·0%)

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Halliday et al. 2021 Sep 18;398(10305):1065-1073

CMS NCD for Carotid Stenting

June 2, 2022

VIA ELECTRONIC MAIL TO NCDREQUEST@CMS.HHS.GOV

Tamara Syrek Jensen, Director
Joseph Chin, Deputy Director
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

CMS opened the NCD for comments 01/12/2023

RE: Formal Request for Reconsideration of NCD 20.7

Dear Ms. Syrek Jensen and Dr. Chin:

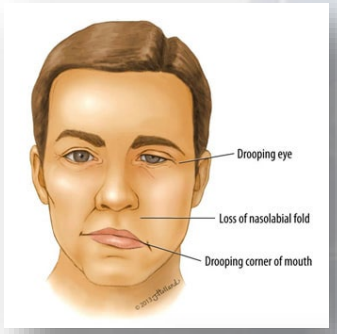
On behalf of the Multispecialty Carotid Alliance (MSCA), we formally request a reconsideration of National Coverage Determination (NCD) 20.7: Percutaneous Transluminal Angioplasty (PTA) that provides coverage for carotid artery stenting (CAS), with the most recent version effective January 1, 2013. The associated National Coverage Analysis is CAG-00085R7: Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting, last updated in December 2009.

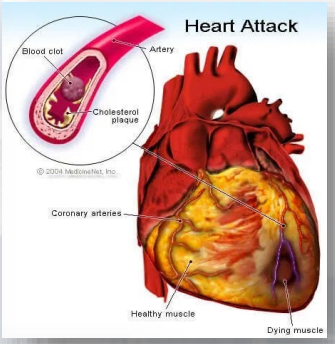
What About TCAR?

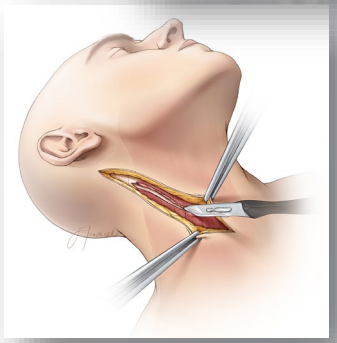
Limitations of CEA

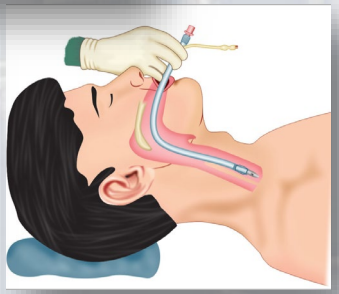
- CNI Risk
- MI Risk
- Incision length (cosmesis)

- General Anesthesia
- Procedure time
- Length of Stay
- Bleeding Risk

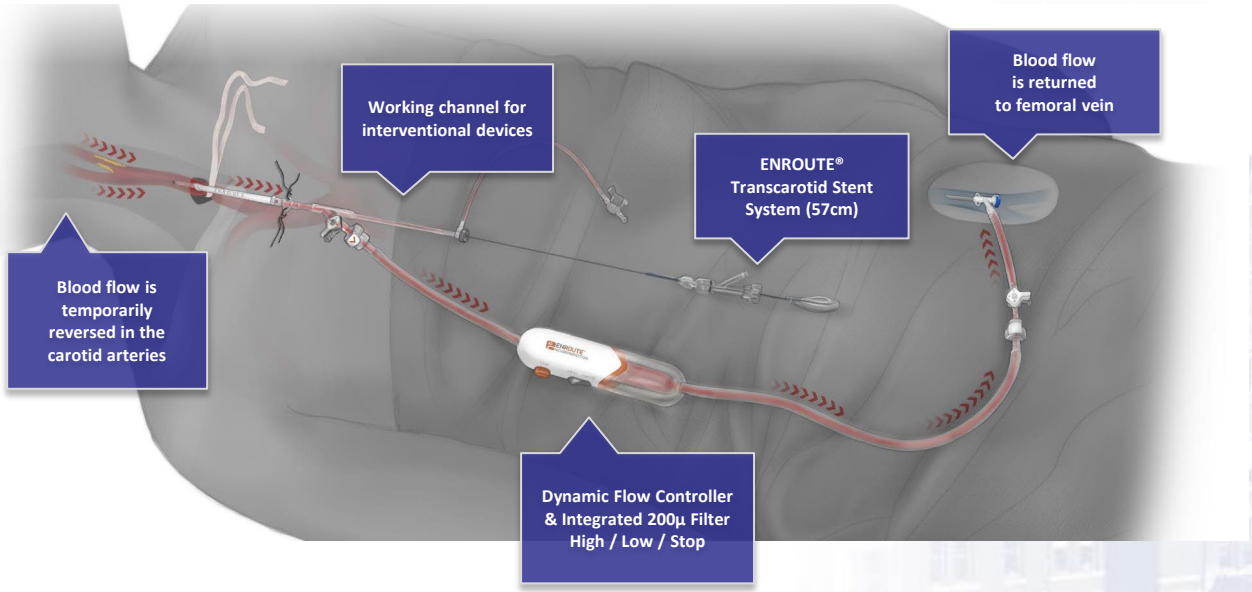








Proximal Protection with Flow Reversal



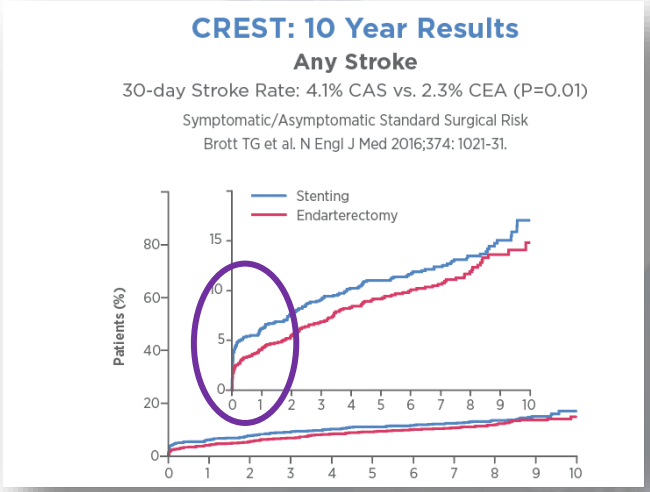
Avoids the arch
Proximal protection
Protects prior to crossing
Improved particle capture

Proximal Protection with Flow Reversal

Limitations of TF-CAS

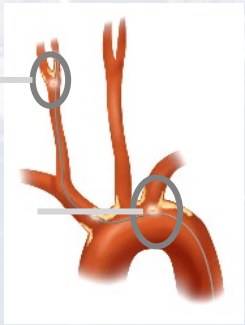
- Previous efforts to move to a less invasive procedure have not been successful

- TCAR is different
  - Avoids pitfalls experienced during TF-CAS
  - Practices that have adopted TCAR have seen benefits in overall carotid outcomes



Pitfalls of a TF approach

- Crossing the lesion
- Crossing the aortic arch

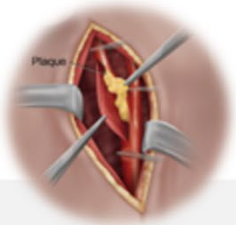


The Arch is a Source of Stroke

Study	Procedure	Embolic Protection	Patients	New Ipsilateral DW-MRI Lesions
ICSS[2]	CEA	Clamp, backbleed	107	17%
PROFI[1]	Transfemoral CAS	Proximal occlusion (MoMA)	31	45%
ICSS[2]	Transfemoral CAS	Distal filter (various)	51	73%
PROFI[1]	Transfemoral CAS	Distal filter (Emboshield)	31	87%
PROOF[3]	TCAR	Proximal clamp, reversed flow	56	18%

1. Bijuklic K, et al. The PROFI study (Prevention of Cerebral Embolization by Proximal Balloon Occlusion Compared to Filter Protection During Carotid Artery Stenting): a prospective randomized trial. *J Am Coll Cardiol*. 2012;59(15):1383-1389.
2. Bonati LH, et al. New ischaemic brain lesions on MRI after stenting or endarterectomy for symptomatic carotid stenosis: a substudy of the International Carotid Stenting Study (ICSS). *Lancet Neurol*. 2010 Apr;9(4):353-62.
3. Alpaslan A, et al. Transcarotid Artery Revascularization With Flow Reversal. *J Endovasc Ther*. 2017 Apr;24(2):265-270

Evolution of Carotid Revasc



1ST Successful CEA performed in **1953** Dr. Michael DeBakey

1990s

Trans Femoral Carotid Stenting

From 1994

- CREST
- SAPPHIRE

VQI TSP

From 2012

- PROOF
- ROADSTER
- ROADSTER2

TCAR for High-Risk Patients

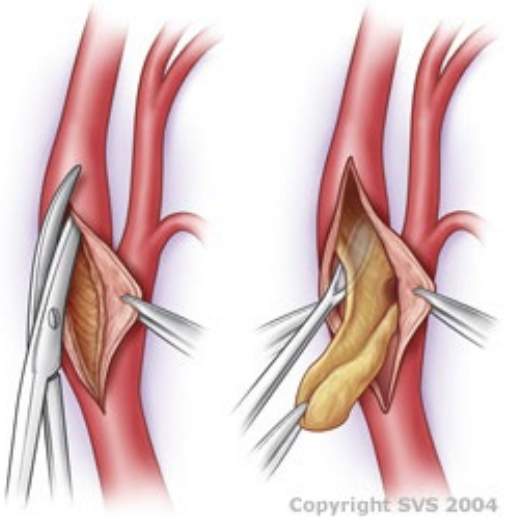
VQI Presentation of TCAR in **Standard Surgical Risk Patients**
Liang et al, VAM 2021

2021 *2022*

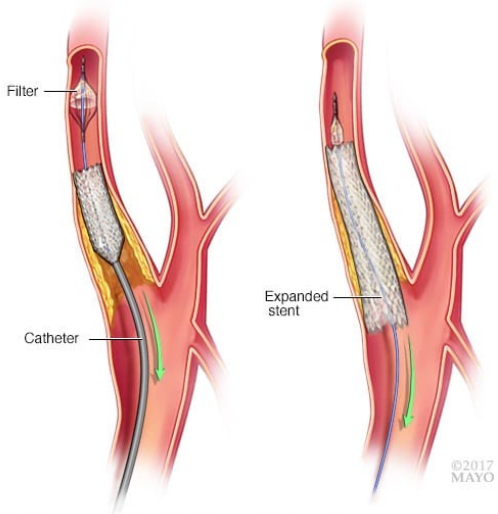
FDA Label Expansion of TCAR for **SSR Patients**

Carotid Revascularization

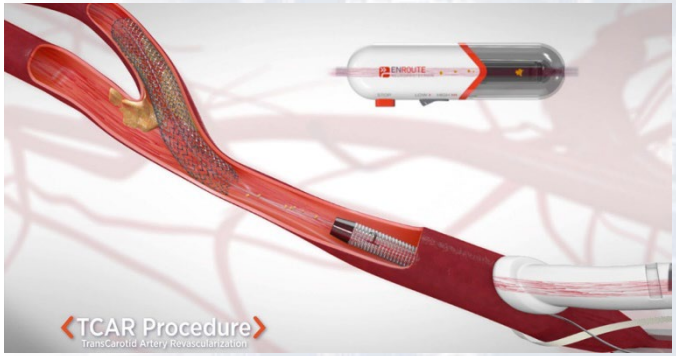
Carotid Endarterectomy (CEA)



Transfemoral Carotid Stenting (TFCAS)



TransCarotid Artery Revascularization (TCAR)



TCAR Outcomes

ROADSTER (N=208)

- Prospective, single arm, multi-center trial of TCAR Procedure
- High surgical risk patients
  - Symptomatic stenosis ≥50% stenosis
  - Asymptomatic stenosis ≥70% stenosis

30-day stroke (ITT) = 1.4%

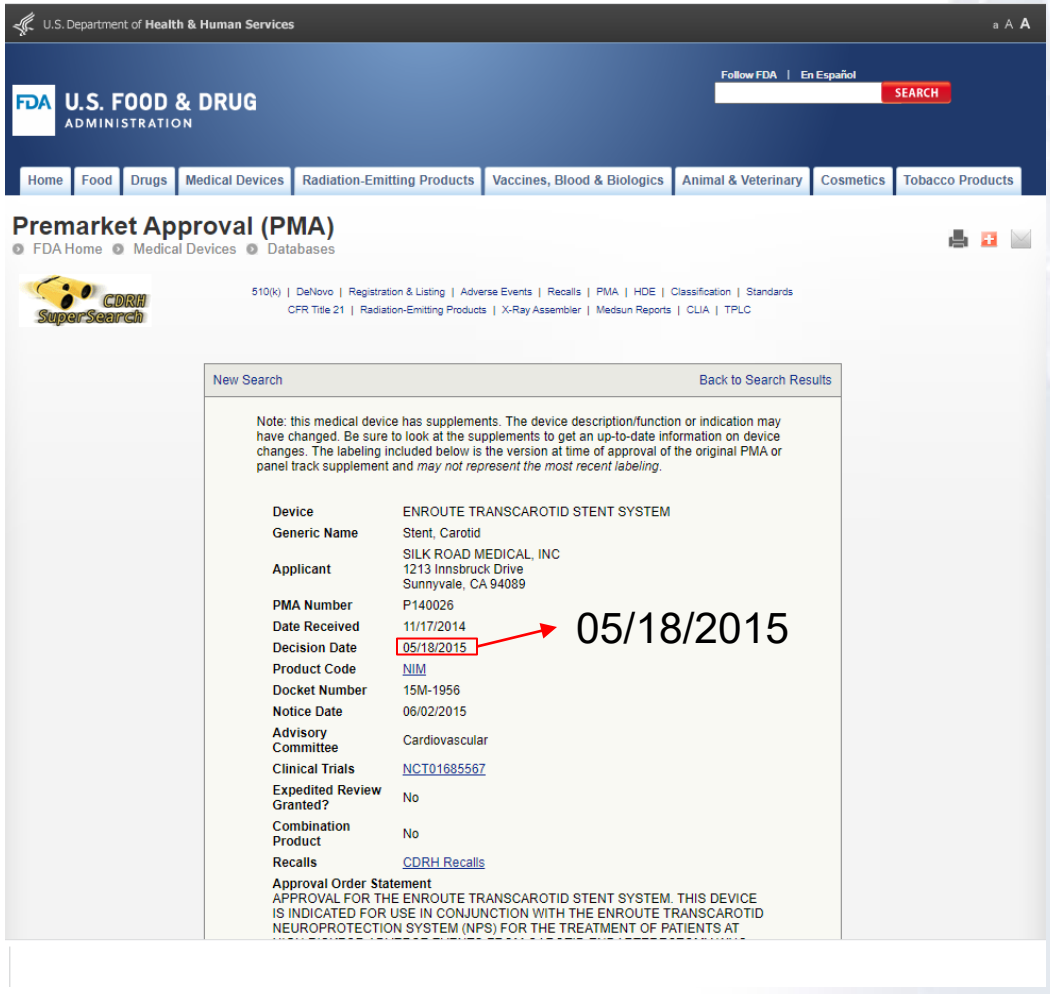
ROADSTER 2 (N=692)

- Prospective, open label, single arm, multicenter, post approval registry for patients undergoing TCAR
- High surgical risk patients
  - Symptomatic stenosis ≥50%
  - Asymptomatic stenosis ≥80%

30-day stroke (ITT) = 1.9%

Kwolek CJ et al. Vasc Surg. 2015 Nov;62(5):1227-34
Kashyap et al. Stroke. 2020 Sep;51(9):2620-2629.

TCAR: FDA Approval



Original CMS Coverage - TCAR

ONE risk factor qualifies patient for CMS high surgical risk status

- **Age ≥75**
- **Prior head/neck surgery or irradiation**
- **Restenosis post CEA**
- **Contralateral occlusion**
- **Surgically inaccessible lesion**
- **Severe tandem lesions**
- Bilateral stenosis requiring treatment
- Cervical spine immobility
- Uncontrolled diabetes
- LVEF <30%
- Chronic renal insufficiency (Creatinine ≥2.5 mg/dl)
- Need for open heart surgery
- MI >72hr & <6 weeks prior to procedure
- Permanent contralateral cranial nerve injury
- Severe pulmonary disease
- >2 diseased coronaries with ≥70% stenosis
- CHF with NYHA Class III or IV
- Need for major surgery (including vascular)
- Unstable angina
- Abnormal stress test
- Laryngeal palsy or laryngectomy

1. HSR, Symptomatic >50% stenosis
2. HSR, Asymptomatic ≥80% stenosis

› **Covered through TCAR Surveillance Project (TSP)**

HIGH RISK PATIENTS

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TCAR Anatomy

- Anatomic Requirements
  - >5cm = Working distance from clavicle to bifurcation ("access to lesion")
  - >6mm= CCA reference diameter
  - CCA free of significant disease for safe sheath insertion and vessel occlusion
- Lesion Morphology
  - Circumferential calcium
  - Fresh thrombus

} Contraindicated

TCAR Surveillance Project

SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TCAR)

ClinicalTrials.gov Identifier: NCT02850588

Recruitment Status : Recruiting
First Posted : August 1, 2016
Last Update Posted : October 7, 2022

See **Contacts and Locations**

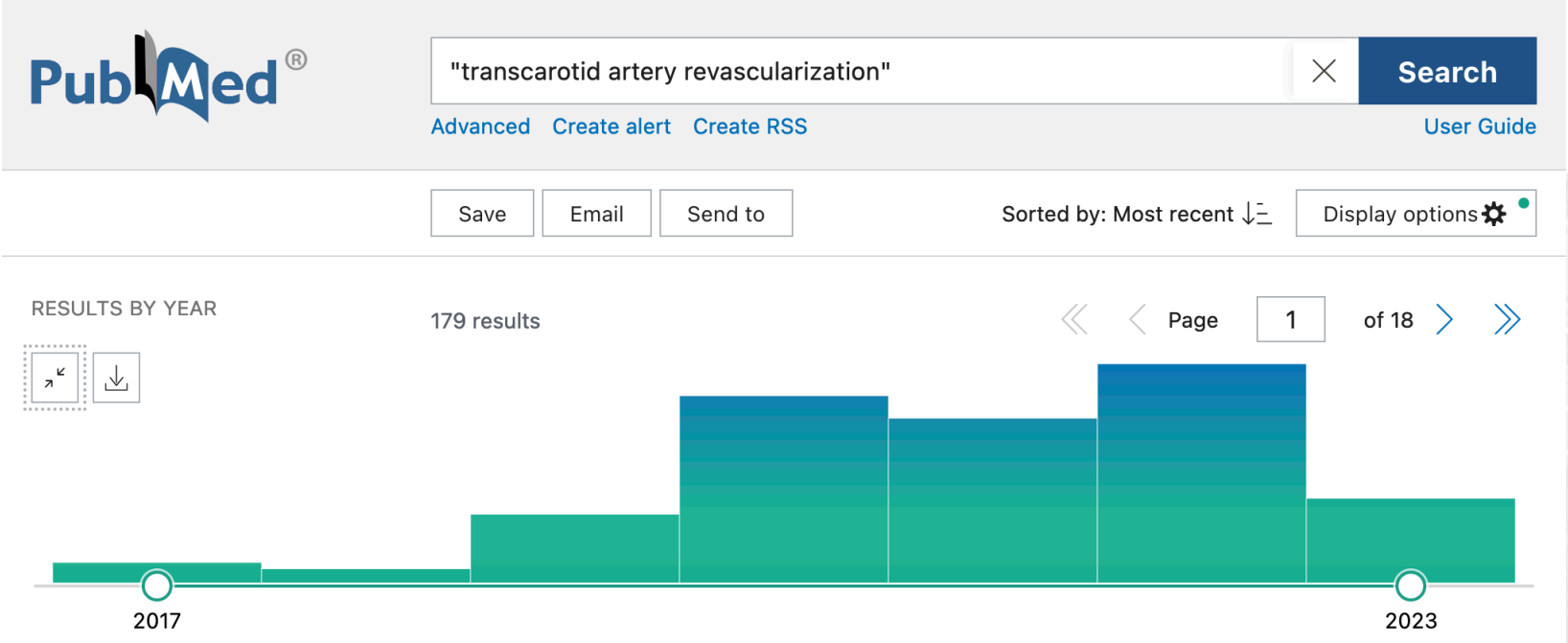
Sponsor:
Society for Vascular Surgery Patient Safety Organization

Information provided by (Responsible Party):
Society for Vascular Surgery Patient Safety Organization

Study Design

Study Type :	Observational [Patient Registry]
Estimated Enrollment :	60000 participants
Observational Model:	Case-Control
Time Perspective:	Prospective
Target Follow-Up Duration:	1 Year
Official Title:	TransCarotid Revascularization Surveillance Project of the Society for Vascular Surgery Vascular Quality Initiative
Actual Study Start Date :	November 1, 2016
Estimated Primary Completion Date :	December 31, 2026
Estimated Study Completion Date :	December 31, 2027

TCAR Publications



Majority based on VQI-TSP data

TCAR Surveillance Project

Ann Surg. 2022 Aug 1;276(2):398-403. doi: 10.1097/SLA.0000000000004496. Epub 2020 Sep 15.

TransCarotid Revascularization With Dynamic Flow Reversal Versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project

Mahmoud B Malas [1], Hanaa Dakour-Aridi [1], Vikram S Kashyap [2], Jens Eldrup-Jorgensen [3], Grace J Wang [4], Raghu L Motaganahalli [5], Jack L Cronenwett [6], Marc L Schermerhorn [7]

- TCAR vs. CEA
- 2016-2019
- 53,869 patients
- Propensity matched

In-Hospital Outcome	CEA (N=6384)	TCAR (N=6384	RR (95% CI)
Stroke/death	1.6%	1.6%	1.01 (0.77–1.33)
Death	0.3%	0.4%	1.14 (0.64–2.02)
Ipsilateral stroke	1.0%	1.2%	1.21 (0.87–1.68)
Myocardial infarction	0.9%	0.5%	0.53 (0.35–0.83)
Stroke/death/MI	2.4%	2.0%	0.85 (0.67–1.07)
Cranial nerve injury	2.7%	0.4%	0.14 (0.08–0.23)

TCAR Surveillance Project

› Ann Surg. 2022 Aug 1;276(2):398-403. doi: 10.1097/SLA.0000000000004496. Epub 2020 Sep 15.

TransCarotid Revascularization With Dynamic Flow Reversal Versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project

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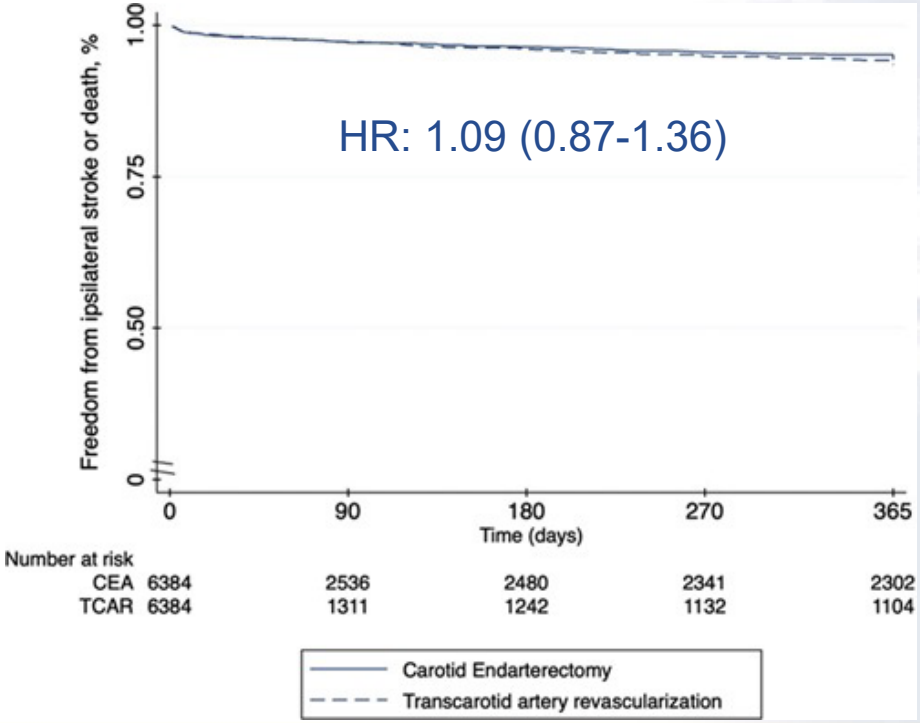

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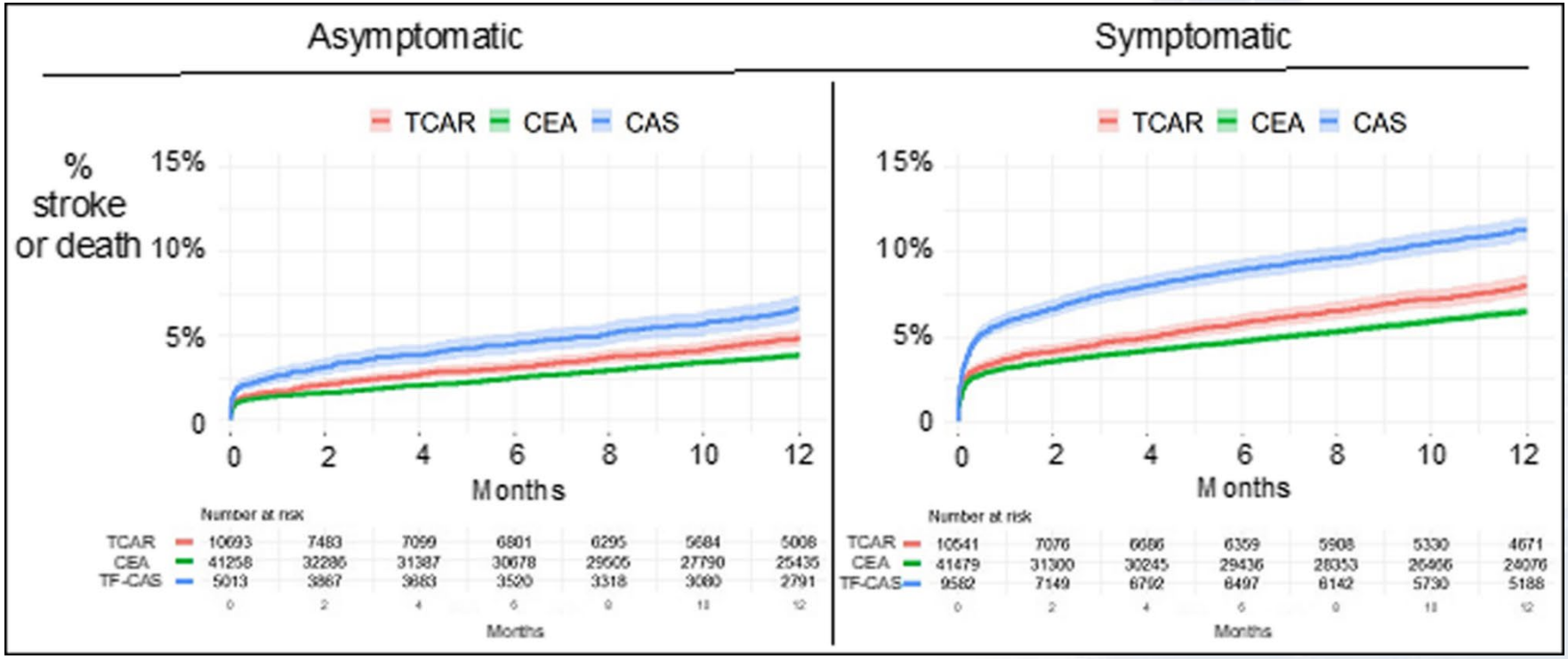
TCAR by Symptom Status



CEA vs. TCAR: HR 1.04 (0.77, 2.80)

CEA vs. TCAR: HR 1.30 (1.04, 1.64)

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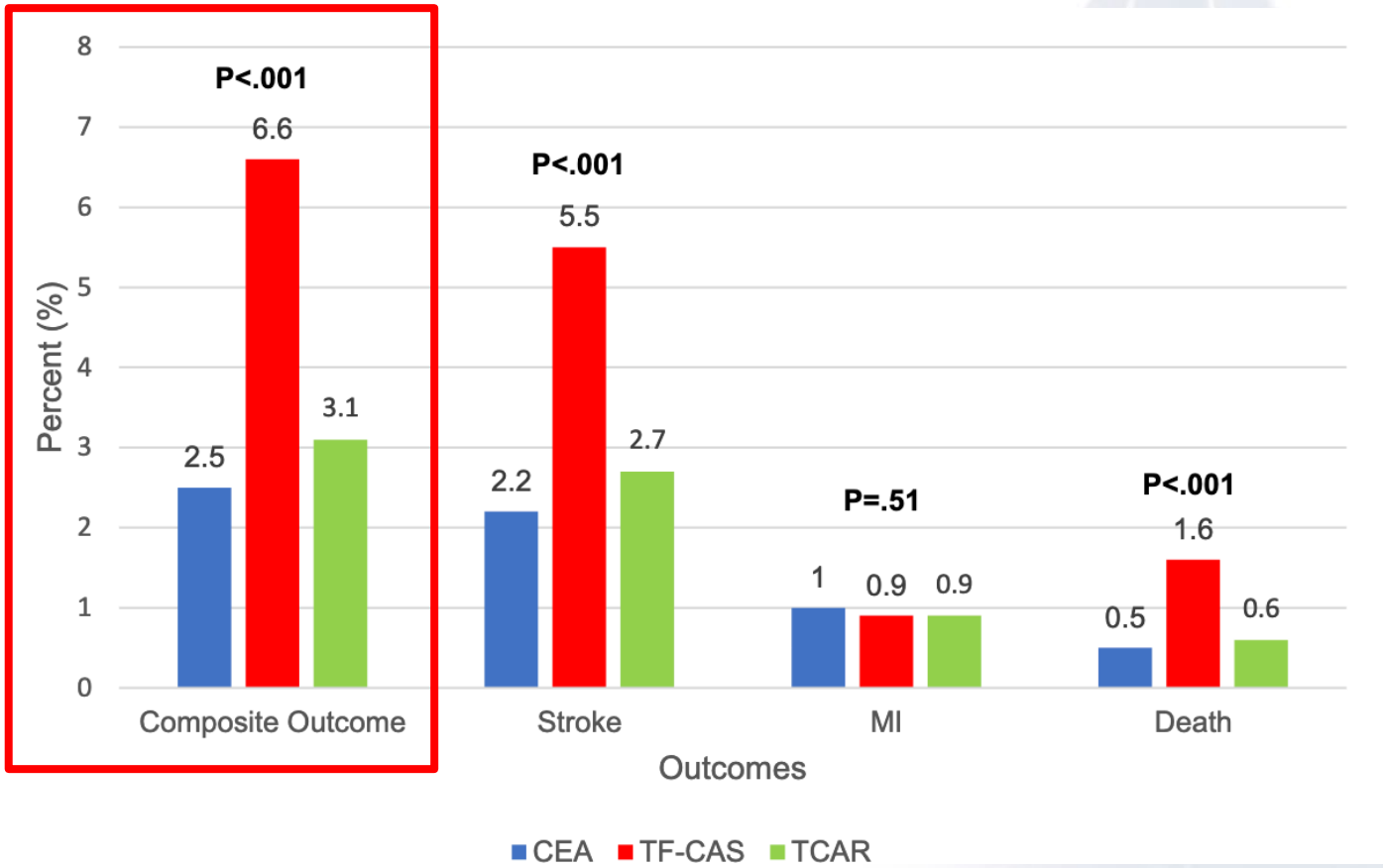
Columbo et al. J Am Heart Assoc. 2022 Oct;11(19):e024964.

TCAR for Octogenarians



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Kibrik et al., J Vasc Surg. 2022 Sep;76(3):769-777.e2.

TCAR for Octogenarians

Table II. Multivariable logistic regression analyses of perioperative (30-day) outcomes stratified by procedure[a]

Perioperative outcome	CEA	TCAR	TF-CAS
Stroke	1.00 (Ref)	1.53 (1.19-1.97)	3.34 (2.61-4.29)
Myocardial infarction	1.00 (Ref)	0.59 (0.40-0.87)	0.56 (0.34-0.90)
Death	1.00 (Ref)	1.29 (0.82-2.02)	3.56 (2.45-5.16)
Composite stroke/death	1.00 (Ref)	1.49 (1.18-1.87)	3.35 (2.65-4.23)

CEA, Carotid endarterectomy; *Ref*, reference; *TCAR*, transcarotid artery revascularization; *TF-CAS*, transfemoral carotid artery stenting.
Data presented as adjusted odds ratio (95% confidence interval).
[a]The full multivariable models are provided in Supplementary Tables II to V (online only).

Kibrik et al., J Vasc Surg. 2022 Sep;76(3):769-777.e2.

TCAR for Octogenarians

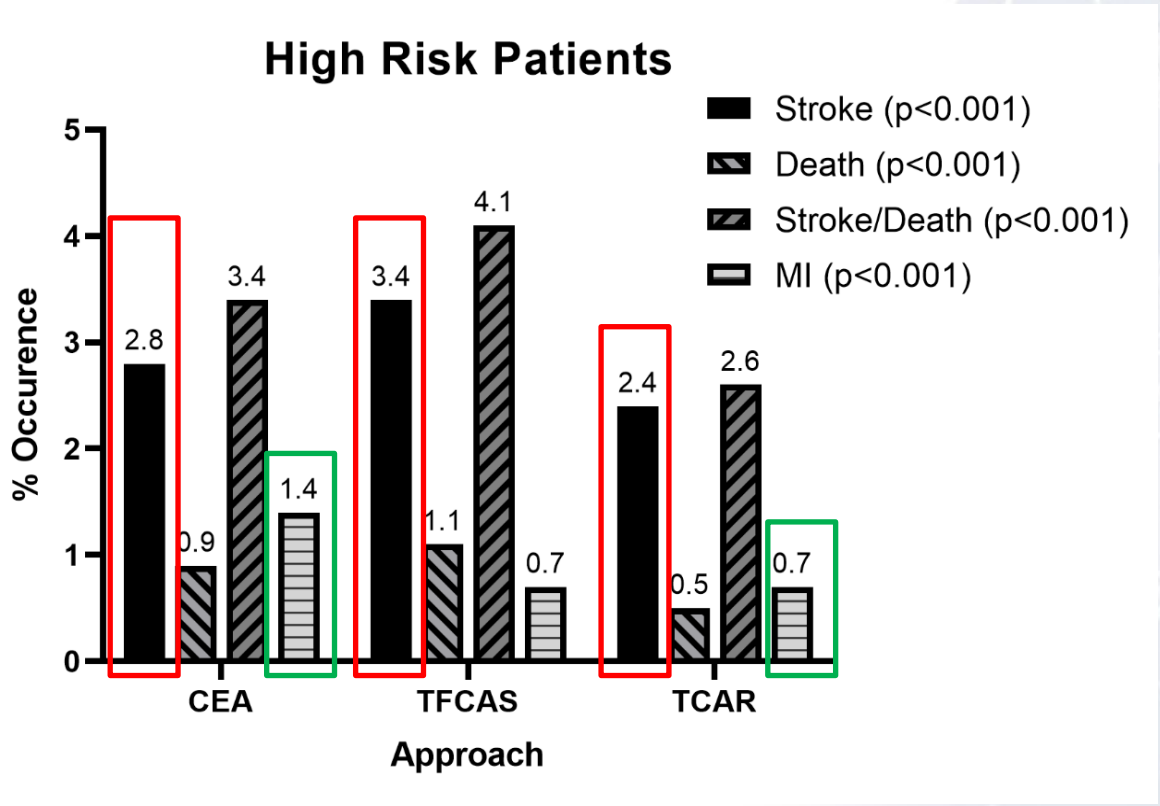
Table IV. Multivariable logistic regression analyses of perioperative (30-day) stroke/death stratified by procedure, symptom status, and degree of stenosis

Variable	CEA	TCAR	TF-CAS
Symptomatic patients	1.00 (Ref)	1.19 (0.89-1.58)	2.59 (2.01-3.34)
Asymptomatic patients	1.00 (Ref)	2.04 (1.41-2.94)	4.36 (3.07-6.20)
Moderate-grade stenosis	1.00 (Ref)	1.35 (0.99-1.83)	3.22 (2.28-4.54)
High-grade stenosis	1.00 (Ref)	1.49 (1.11-2.05)	3.35 (2.41-4.79)

CEA, Carotid endarterectomy; *Ref*, reference; *TCAR*, transcarotid artery revascularization; *TF-CAS*, transfemoral carotid artery stenting.
Data presented as adjusted odds ratio (95% confidence interval).

Kibrik et al., J Vasc Surg. 2022 Sep;76(3):769-777.e2.

TCAR for High-Risk Patients



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Zhang et al., J Vasc Surg. 2022 Aug;76(2):474-481.e3.

TCAR for High-Risk Patients

Table II. Relationship between approach and adverse outcomes among Centers for Medicare & Medicaid Services (CMS) high-risk patients, after stratification by approach

	Unadjusted		Adjusted	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Stroke[a]				
Approach				
CEA	Ref		Ref	
TFCAS	1.25 (1.05-1.48)	.013	1.23 (1.03-1.46)	.021
TCAR	0.86 (0.72-1.03)	.103	0.82 (0.68-0.99)	.037
Death[b]				
Approach				
CEA	Ref		Ref	
TFCAS	1.14 (0.85-1.54)	.378	1.20 (0.89-1.62)	.241
TCAR	0.49 (0.34-0.70)	<.001	0.50 (0.35-0.72)	<.001
Stroke/death[c]				
Approach				
CEA	Ref		Ref	
TFCAS	1.24 (1.06-1.45)	.008	1.20 (1.03-1.41)	.021
TCAR	0.77 (0.65-0.91)	.003	0.73 (0.61-0.86)	<.001
MI[d]				
Approach				
CEA	Ref		Ref	
TFCAS	0.49 (0.36-0.67)	<.001	0.45 (0.33-0.62)	<.001
TCAR	0.48 (0.36-0.65)	<.001	0.46 (0.33-0.62)	<.001

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Zhang et al., J Vasc Surg. 2022 Aug;76(2):474-481.e3.

TCAR for High-Risk Patients

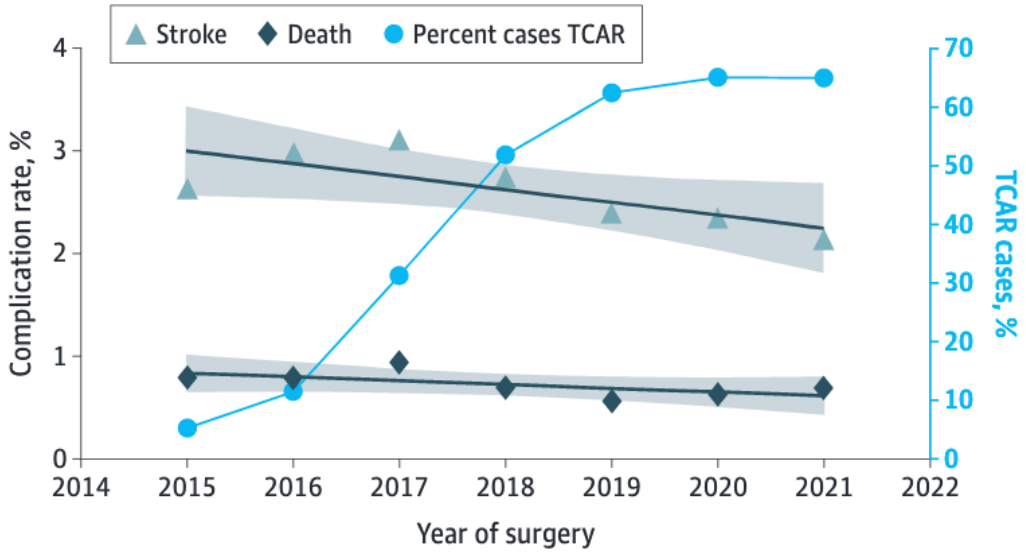

Table. Association of Year of Surgery and Operative Approach With In-Hospital Complications Among High-risk Patients Undergoing Carotid Artery Stenting, Vascular Quality Initiative 2015-2021

	Stroke			Death		
	aOR (95% CI)		Excess benefit explained model 2 vs 1, %	aOR (95% CI)		Excess benefit explained model 2 vs 1, %
Factor	Model 1[a]	Model 2[b]		Model 1[a]	Model 2[b]	
Year of surgery, per year	0.90 (0.87-0.94)	0.93 (0.89-0.96)	30	0.88 (0.82-0.95)	0.96 (0.89-1.03)	67
TCAR (vs TFCAS)	NA	0.75 (0.65-0.88)		NA	0.42 (0.29-0.61)	

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Stonko et al., JAMA Surg. 2023 Apr 12;e228384.

What About Standard Risk?

Journal of Vascular Surgery | SVS Society for Vascular Surgery

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S2: PLENARY SESSION 2 | VOLUME 74, ISSUE 3, E27-E28, SEPTEMBER 01, 2021

Expansion of Transcarotid Artery Revascularization to Standard Risk Patients for Treatment of Carotid Artery Stenosis

Patric Liang • Jack Cronenwett • Eric Secemsky • ... Vikram S. Kashyap • Raghu L. Motaganahalli • Marc L. Schermerhorn • Show all authors

DOI: https://doi.org/10.1016/j.jvs.2021.06.048

› JAMA Neurol. 2023 Mar 20;e230285. doi: 10.1001/jamaneurol.2023.0285. Online ahead of print.

Risk of Stroke, Death, and Myocardial Infarction Following Transcarotid Artery Revascularization vs Carotid Endarterectomy in Patients With Standard Surgical Risk

Patric Liang [1], Jack L Cronenwett [2], Eric A Secemsky [3], Jens Eldrup-Jorgensen [4], Mahmoud B Malas [5], Grace J Wang [6], Brian W Nolan [4], Vikram S Kashyap [7], Raghu L Motaganahalli [8], Marc L Schermerhorn [1]

Affiliations + expand

PMID: 36939697 PMCID: PMC10028539 (available on 2024-03-20)
DOI: 10.1001/jamaneurol.2023.0285

› J Vasc Surg. 2022 Aug;76(2):474-481.e3. doi: 10.1016/j.jvs.2022.03.860. Epub 2022 Mar 31.

Transcarotid artery revascularization is associated with similar outcomes to carotid endarterectomy regardless of patient risk status

George Q Zhang [1], Sanuja Bose [2], David P Stonko [3], Christopher J Abularrage [4], Devin S Zarkowsky [5], Caitlin W Hicks [6]

Affiliations + expand

PMID: 35367564 PMCID: PMC9329175 (available on 2023-08-01) DOI: 10.1016/j.jvs.2022.03.860

What About Standard Risk?

	OR (95% CI)
Stroke	
CEA	Ref
TFCAS	1.60 (1.37-1.86)
TCAR	1.05 (0.84-1.31)
Death	
CEA	Ref
TFCAS	3.35 (2.47-4.54)
TCAR	1.58 (0.97-2.56)
MI	
CEA	Ref
TFCAS	1.77 (1.54-2.04)
TCAR	1.11 (0.91-1.37)

Adjusted for age, sex, smoking status, hypertension, diabetes, coronary artery disease, and congestive heart failure stage I/II

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Zhang et al. J Vasc Surg. 2022 Aug;76(2):474-481.e3

TCAR for Standard Risk

- TCAR vs. CEA
- 2016-2019
- 38,025 patients
- Propensity matched

Table 3. Thirty-Day and 1-Year Outcomes After Transcarotid Artery Stenting or Carotid Endarterectomy Stenting in a Propensity Score–Matched Study Population Using Kaplan-Meier Estimates

	%				
	Transcarotid artery stenting	Carotid endarterectomy	Absolute difference, % (95% CI)	Relative risk (95% CI)	*P* value
30-d Stroke/death/MI and 1-y ipsilateral stroke[a]	3.0	2.6	0.40 (−0.43 to 1.24)	1.14 (0.87 to 1.50)	.34
30-d					
Stroke/death	1.8	1.5	0.34 (−0.18 to 0.90)	1.24 (0.90 to 1.71)	.21
Stroke	1.6	1.1	0.42 (−0.06 to 0.93)	1.38 (0.97 to 1.96)	.07
Death	0.3	0.4	−0.07 (−0.33 to 0.18)	0.84 (0.42 to 1.69)	.62
Stroke/death/MI[a]	2.2	2.1	0.15 (−0.48 to 0.74)	1.07 (0.81 to 1.42)	.63
1-y					
Ipsilateral stroke	1.6	1.1	0.52 (0.03 to 1.08)	1.49 (1.05 to 2.11)	.02
Death	2.6	2.5	0.13 (−0.18 to 0.33)	1.04 (0.78 to 1.39)	.67

Liang et al., JAMA Neurol. 2023 Mar 20;e230285.

Standard Risk Approval

May, 2022

SILKROAD MEDICAL®

Silk Road Medical Announces FDA Approval of Expanded Indications for the ENROUTE® Transcarotid Stent System

SUNNYVALE, Calif. – May 2, 2022 – Silk Road Medical, Inc. (Nasdaq: SILK), a company focused on reducing the risk of stroke and its devastating impact, today announced that that the U.S. Food and Drug Administration (FDA) approved expanded indications for the ENROUTE stent to include patients at standard risk for adverse events from carotid endarterectomy (CEA). Previously, the stent was approved for use only in patients with anatomic or physiological criteria that put them at high risk of complications from more invasive surgical procedures.

Original Investigation | Surgery

September 16, 2022

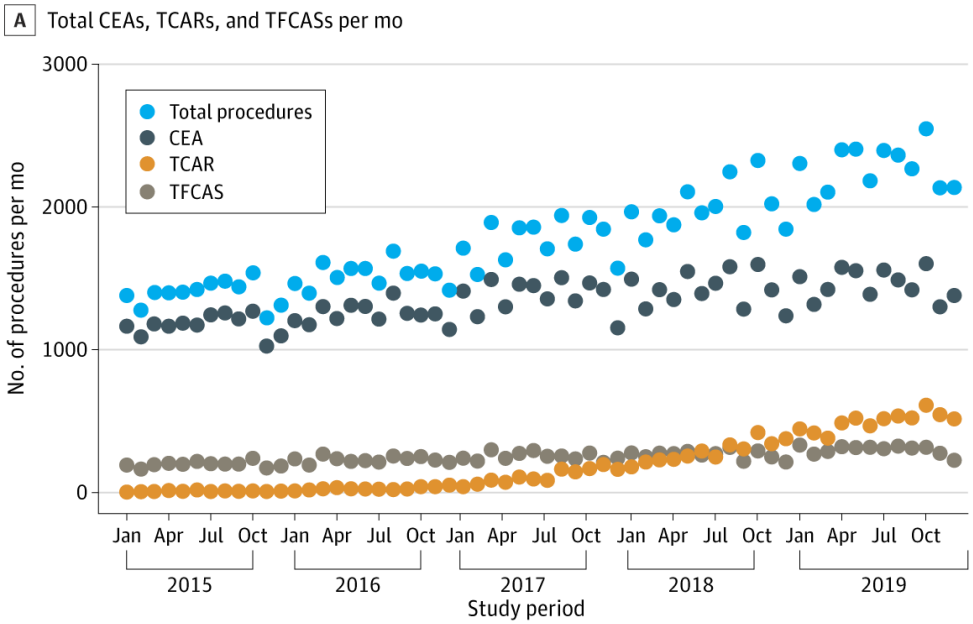
Use of Transcarotid Artery Revascularization, Transfemoral Carotid Artery Stenting, and Carotid Endarterectomy in the US From 2015 to 2019

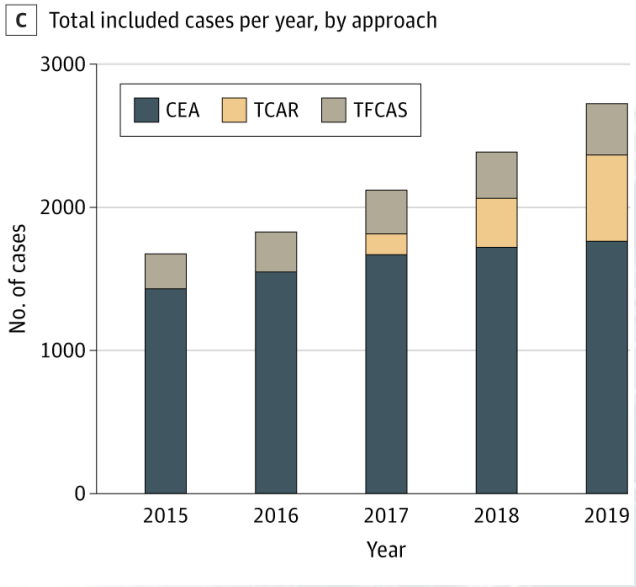
David P. Stonko, MD, MS[1,2]; Earl Goldsborough III, BS[3]; Pavel Kibrik, DO[4]; et al

» Author Affiliations | Article Information

JAMA Netw Open. 2022;5(9):e2231944. doi:10.1001/jamanetworkopen.2022.31944

- VQI Data
- N=108,676
- Jan 2015 to Dec 2019





Heart and Vascular Institute

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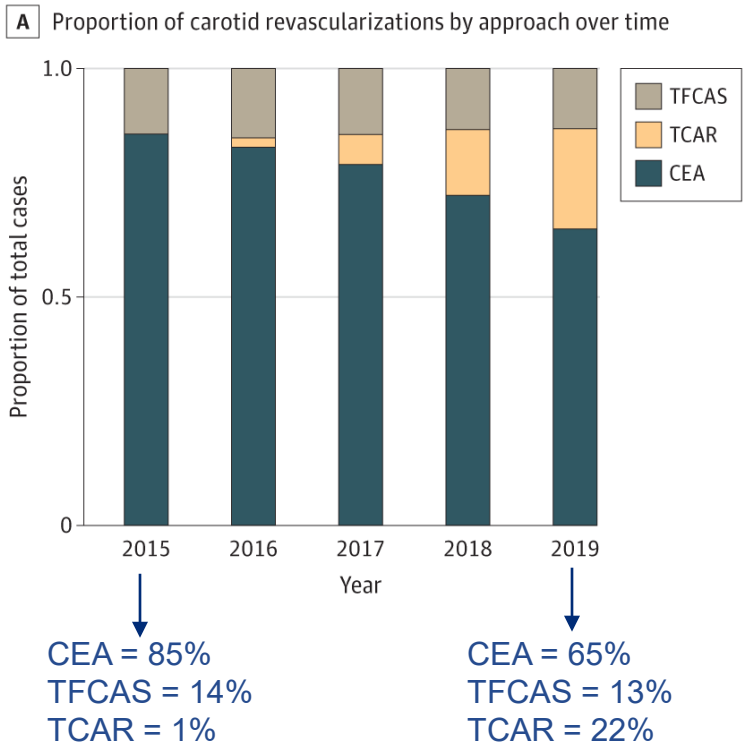
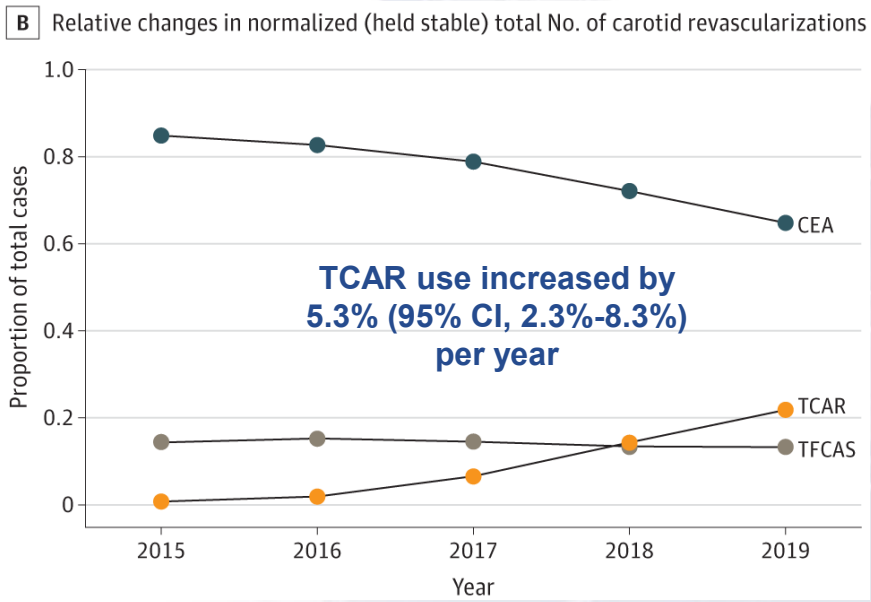


CEA = 85%
TFCAS = 14%
TCAR = 1%

CEA = 65%
TFCAS = 13%
TCAR = 22%



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ALL PATIENTS

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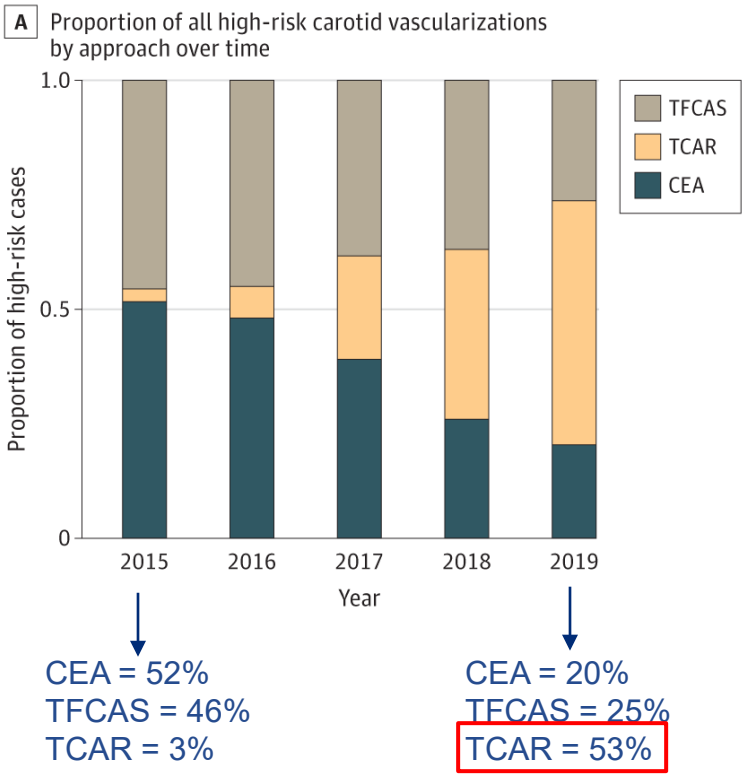
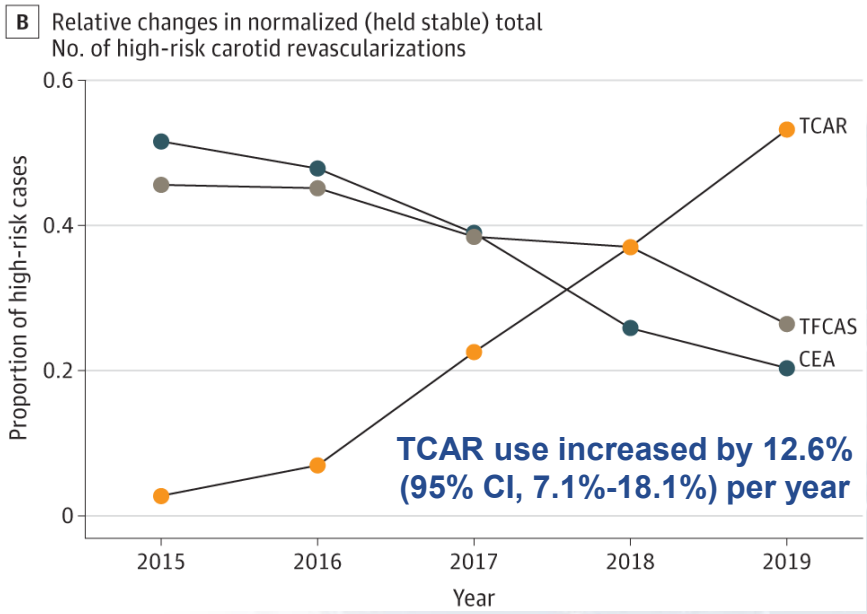


CEA = 52%
TFCAS = 46%
TCAR = 3%

CEA = 20%
TFCAS = 25%
TCAR = 53%



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HIGH RISK PATIENTS

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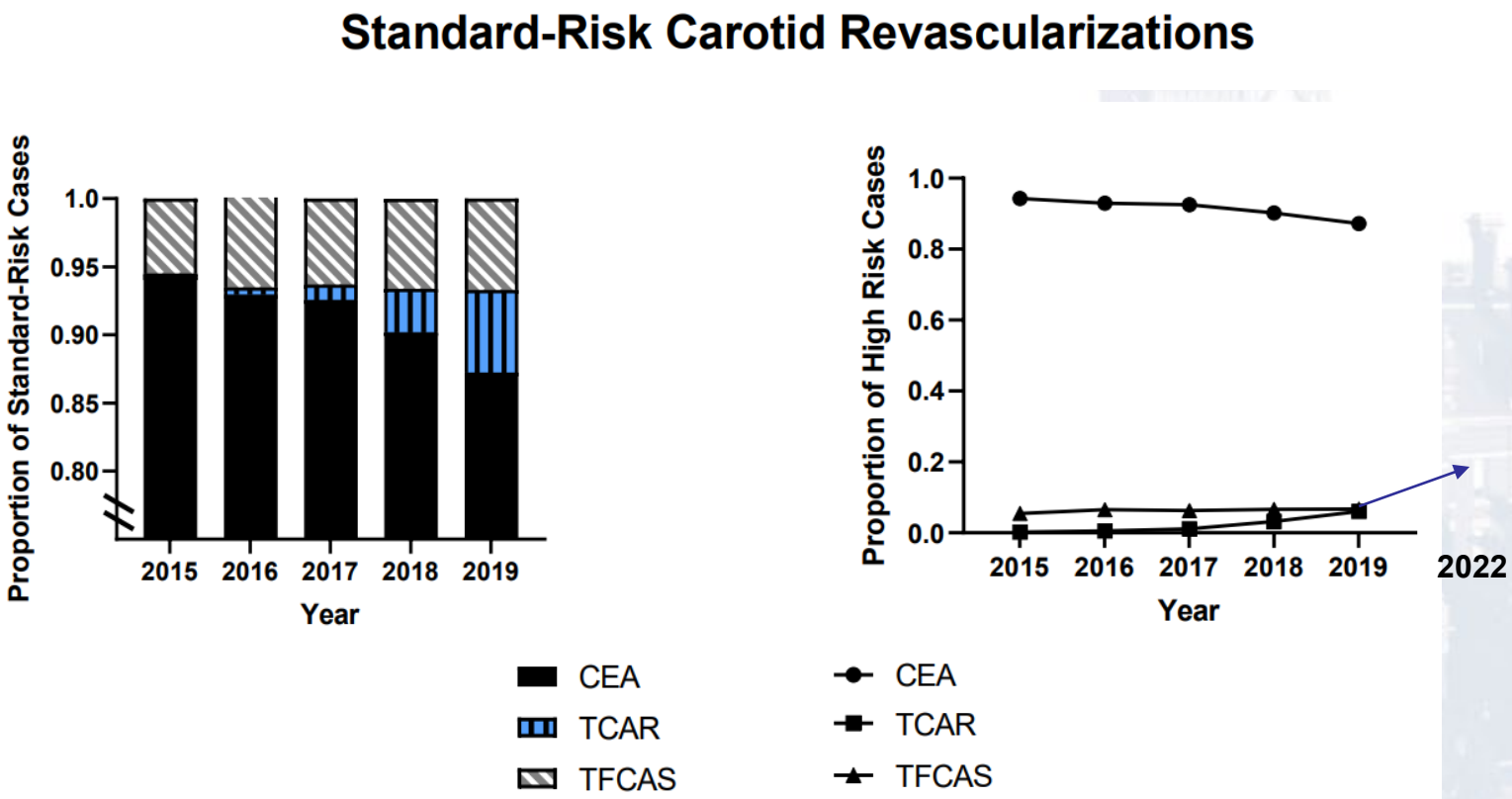
TCAR is Dominant for High-Risk

	RRR (95% CI)	
	High-Risk Status	**Year**
CEA	Reference	Reference
TFCAS	14.1 (11.9, 16.7)	1.1 (1.08, 1.2)
TCAR	36.1 (29.4, 44.7)	2.4 (2.2, 2.7)

Multinomial regression adjusting for age, sex, race and ethnicity, insurance status, comorbidities (hypertension, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, diabetes, and chronic kidney disease or hemodialysis), functional status, smoking status, high-risk vs standard-risk status, degree of, symptomatic status, and year of surgery.

Stonko et al. JAMA Netw Open. 2022;5(9):e2231944.

Standard Risk Adoption



- VQI Data
- N=108,676
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TCAR Limitations

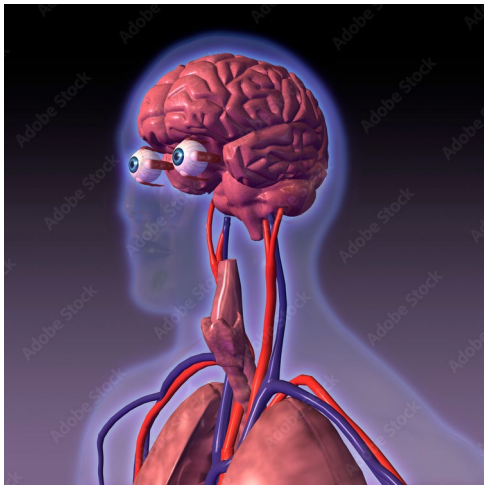
- Anatomic requirements → “cherry-picking” cases?
- Close oversight of cases by industry → ? long term sustainability
- Limited comparative data → data biases
  - Roadster 1, 2, 3 data
  - VQI-TSP
  - RCT not financially viable (likely)
- Emerging technology / applications off-IFU
  - Hard to study

Is There Bias in TCAR Data?

Bias Type	Description
Selection	Different prognoses between groups
Channeling	Treatment decision based on prognostic features
Chronology	Different timing of interventions
Detection	Nonuniform measuring methods
Ascertainment	Different availability of data / outcomes reporting
Performance	Nonuniform intervention
Publication	Distorted data reporting
Optimism	Underlying belief that new is better
Conflicts of Interest	Competing interests

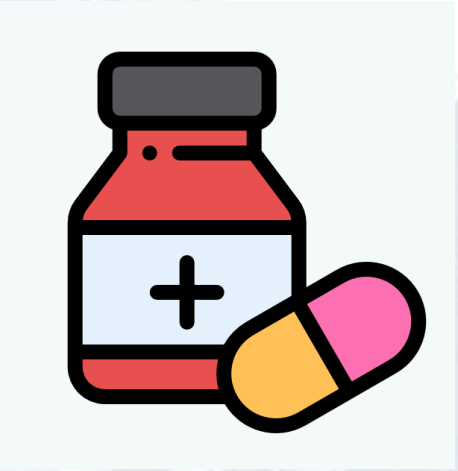
Selection & Channeling Biases

Anatomic Criteria



Risk Status

Med Compliance



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Detection & Ascertainment Biases

Stroke Definition	Data Capture	Data Reporting
	ROADSTER 1/2 SVS | VQI *In collaboration with NCDR®* Claims: 37215	
✓	✓	✓

Performance Bias

Rx Protocol

IFU Reporting

New Technology

SHOCKWAVE MEDICAL

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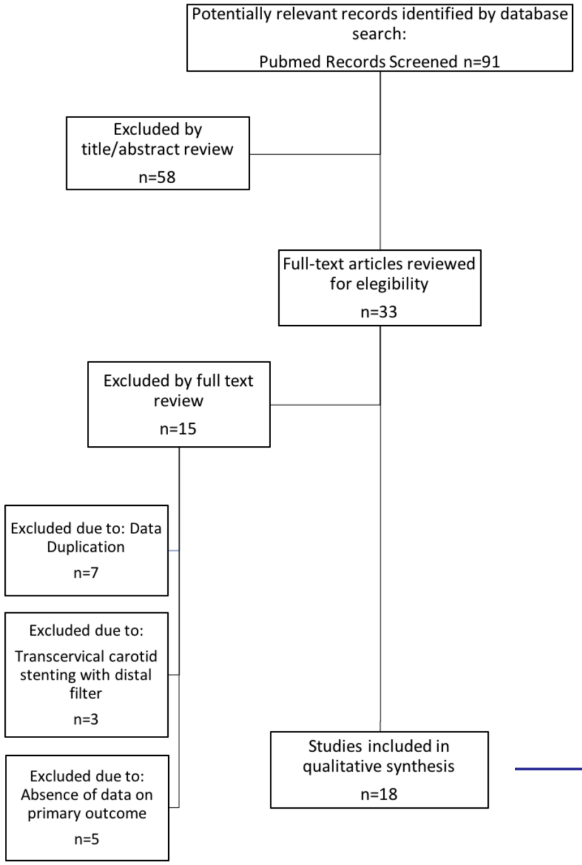
Publication Bias



Through March 2020

- High-Quality Studies • N = 0
- Moderate-Quality Studies • N = 6
- Poor-Quality Studies • N = 12

Coelho et al., Stroke. 2020 Sep;51(9):2863-2871.

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Optimism and COI Biases

New Technology

COI

ROADSTER 1/2

OPEN PAYMENTS™

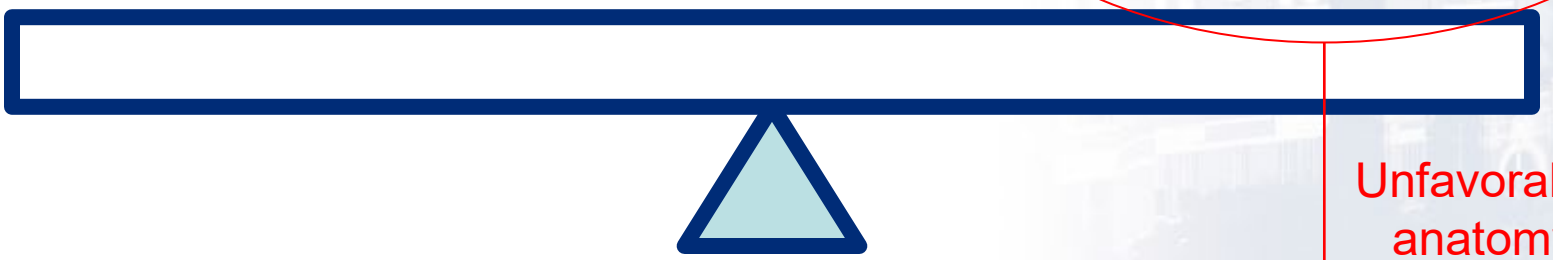
TCAR vs. CEA in Practice

Clear advantage CEA

- Low bifurcation (CCA <5cm)
- Significant CCA disease
- Lesions with prohibitive calcium
- ICA diameter >9mm or <4mm
- Liquid thrombus

Clear advantage TCAR

- High bifurcation
- Hostile neck (radiation, immobility)
- Reoperative site (CEA restenosis)
- Frail patients
- (Patient prefers less invasive procedure)



Unfavorable anatomy

TF-CAS

TCAR vs. CEA in Practice

Clear advantage CEA

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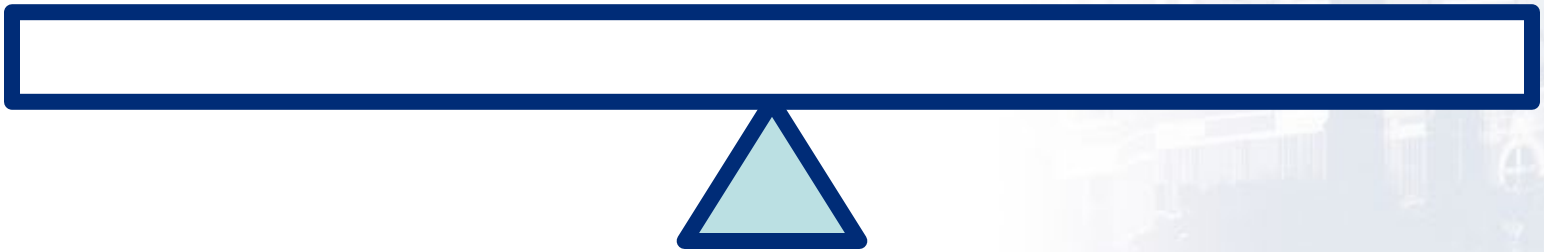

Everything Else → TBD

Conclusions

- TCAR adoption has increased dramatically since 2015
- In general, TCAR > TFCAS
- TCAR = CEA for short term outcomes
  - TCAR ?> CEA for high-risk & symptomatic patients
  - VQI data suggests at least equivalency
- Longer term outcomes (and ideally an RCT) for CEA vs. TCAR needed

Thank You

@CaitlinWHicks

@HopkinsSurgery

@JHHVascular

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