VEITH SYMPOSIUM

Is TCAR Ready to Replace CEA:

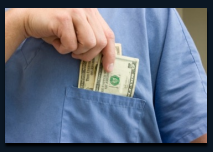
What About the Clinical Results to Date:
What About Clinical Marketing:

How Will We Find Out



Bruce A. Perler, MD, MBA

FINANCIAL DISCLOSURE



I Have No Financial Relationships to Disclose

I Have Performed TCAR

USA TODAY

SAPPHIRE Trial

Stents in neck can prevent stroke

By Steve Sternberg

CHICAGO — Doctors hailed a **"watershed"** **advance** in stroke prevention on Tuesday, one that will **eliminate** the need for thousands of operations and cut the rate of potentially deadly complications in half. The technique is a new form of angioplasty, now commonly used instead of bypass surgery to clear arteries supplying the heart. The new procedure applies similar techniques in the neck. It is designed to be used in place of a risky operation called carotid endarterectomy, which requires doctors to make a 6-inch incision in the neck and carve out two inner layers of the carotid artery supplying the brain.

AHA: November, 2002

SAPPHIRE Trial

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 | OCTOBER 7, 2004 | VOL. 351 NO. 15

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

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

CREST

U.S. Department of Health and Human Services

NIH News

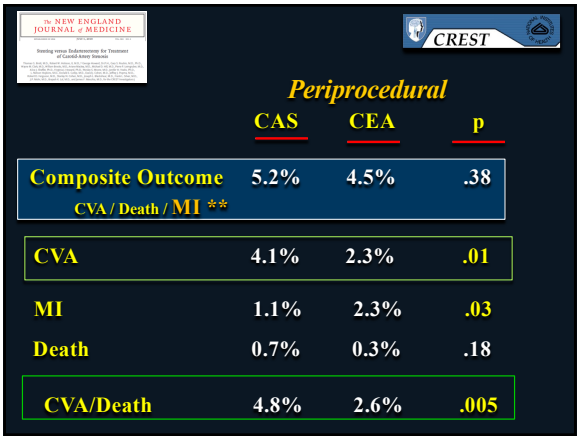
National Institutes of Health

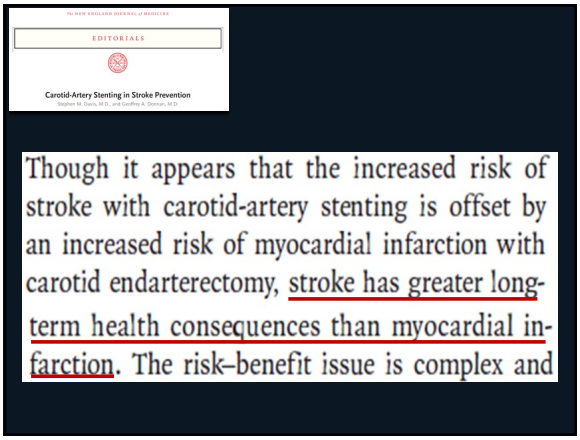
National Institute of Neurological Disorders and Stroke (NINDS)

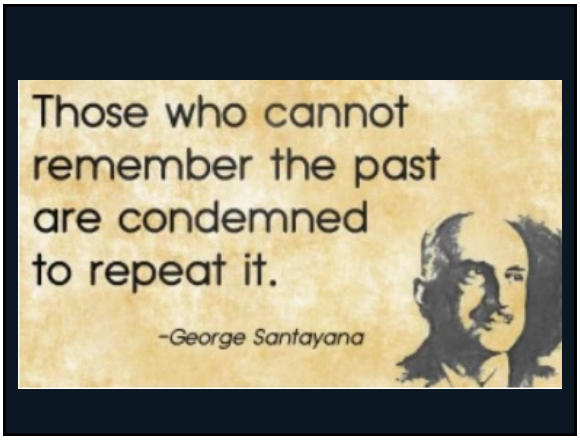
Landmark NIH Clinical Trial Comparing Two Stroke Prevention Procedures Shows Surgery and Stenting Equally Safe and Effective

Opportunities Exist to Target the Treatment to the Patient

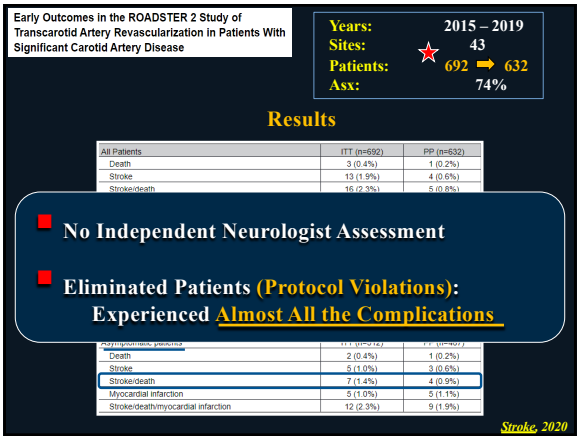
February, 2010

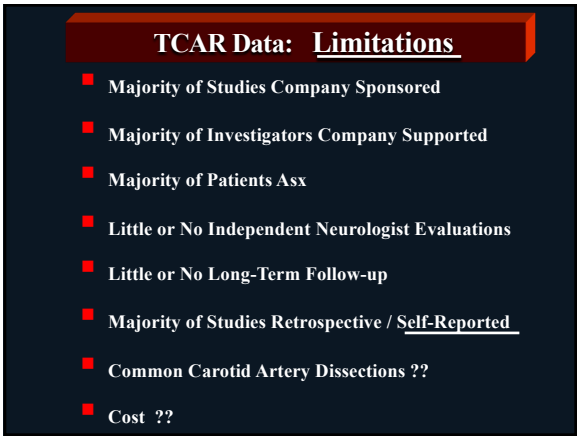

The NEW ENGLAND JOURNAL of MEDICINE
CREST
Periprocedural
CAS CEA p
Composite Outcome CVA / Death / MI ** 5.2% 4.5% .38
CVA 4.1% 2.3% .01
MI 1.1% 2.3% .03
Death 0.7% 0.3% .18
CVA/Death 4.8% 2.6% .005


EDITORIALS
Carotid-Artery Stenting in Stroke Prevention
Though it appears that the increased risk of stroke with carotid-artery stenting is offset by an increased risk of myocardial infarction with carotid endarterectomy, stroke has greater long-term health consequences than myocardial infarction. The risk–benefit issue is complex and


Those who cannot remember the past are condemned to repeat it.
-George Santayana


The TCAR Revolution
The Shifting Paradigm in Carotid Revascularization: TCAR in Real-World Pr
TCAR: Unclogging Carotid Arterie
procedure now available in
NEWS | STENTS CAROTID | JUNE 13, 2019
TCAR Achieves Favorable Outcomes Versus Carotid Endarterectomy in CAD Patients
Updated results of TCAR Surveillance Project presented at Society for Vascular Surgery Vascular Annual Meeting
Saddleback Medical Cen
Offers Groundbreaking TCAR
Proced
Reducing risk of stroke with new technol
TCAR


Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease
Years: 2015 – 2019
Sites: 43
Patients: 692 ➡ 632
Asx: 74%
Results
All Patients ITT (n=692) PP (n=632)
Death 3 (0.4%) 1 (0.2%)
Stroke 13 (1.9%) 4 (0.6%)
Stroke/death 16 (2.3%) 5 (0.8%)
Death 2 (0.4%) 1 (0.2%)
Stroke 5 (1.0%) 3 (0.6%)
Stroke/death 7 (1.4%) 4 (0.9%)
Myocardial infarction 5 (1.0%) 5 (1.1%)
Stroke/death/myocardial infarction 12 (2.3%) 9 (1.9%)
No Independent Neurologist Assessment
Eliminated Patients (Protocol Violations): Experienced Almost All the Complications
Stroke, 2020


TCAR Data: Limitations
Majority of Studies Company Sponsored
Majority of Investigators Company Supported
Majority of Patients Asx
Little or No Independent Neurologist Evaluations
Little or No Long-Term Follow-up
Majority of Studies Retrospective / Self-Reported
Common Carotid Artery Dissections ??
Cost ??

TCAR: *Self-Reported Data*

In-hospital outcomes of transcarotid artery revascularization and carotid endarterectomy in the Society for Vascular Surgery Vascular Quality Initiative

Marc L. Schermerhorn, MD,[a] Patric Liang, MD,[a] Hanaa Dakour-Aridi, MD,[b] Vikram S. Kashyap, MD,[c] Grace J. Wang, MD, MSCE,[d] Brian W. Nolan, MD,[e] Jack L. Cronenwett, MD,[f] Jens Eldrup-Jorgensen, MD,[g] *and* Mahmoud B. M... *and San D... Me, Lebanon, NH, and San D...*

Cranial Nerve Injury

TCAR	0.6%
CEA:	1.8%

p < .001

ABSTRACT

Objective: Tra... carotid revas-... culariza... carotid artery stenting. How... to confirm the safety of TCAR...

Methods: We... to March 2018 using the Soc... the Society for Vascular Surg... composite of in-hospital str...

Results: A tot... its undergoing TCAR were old... they also had more medical... (11%; *P* < .001) chronic obstru... On unadjusted analysis, TCAR h... arction (MI; 2.5% vs 1.9%; *P* = .16) co... cal death (0.3% vs 0.3%; *P* = .88), 30-day death (0.9% vs 0.4%; *P* = .06), or MI (1.1% vs 0.6%; *P* = .11). However, on average, TCAR procedures were 33 minutes shorter than CEA (78 ± 33 minutes vs 111 ± 43 minutes; *P* < .001). Patients undergoing TCAR were also less likely to incur cranial nerve injuries (0.6% vs 1.8%; *P* < .001) and less likely to have a postoperative length of stay >1 day (27% vs 30%; *P* = .046). On adjusted analysis, there was no difference in terms of stroke/death (odds ratio, 1.3; 95% confidence interval, 0.8-2.2; *P* = .28), stroke/death/MI (odds ratio, 1.4; 95% confidence interval, 0.9-2.1; *P* = .18), or the individual outcomes.

Conclusions: Despite a substantially higher medical risk in patients undergoing TCAR, in-hospital stroke/death rates were similar between TCAR and CEA. Further comparative studies with larger samples sizes and longer follow-up will be needed to establish the role of TCAR in extracranial carotid disease management. (J Vasc Surg 2020;71:87-95.)

J Vasc Surg, 2020

TCAR: *Common Carotid Artery Dissection*

Carotid Artery Dissections from TCAR as Reported on the MAUDE Database

Dongjin Suh, Yuchi Ma, Michael Amendola, Daniel H. Newton, Kedar S. Lavingia. Virginia Commonwealth University Health System, Richmond, VA

TCAR

(2016 – 2020)

Conclusions: CD is the most common injury related to TCAR as reported on MAUDE database.

Carotid A Dissections: 58

J Vasc Surg, 2021

TCAR: *Cost*

Carotid Endarterectomy Is the Most Cost-effective Treatment Modality for Nonemergent Significant Carotid Artery Stenosis

Sheila M. Coogan,[a] Amanda Enerson,[a] Humaira Sadat,[b] Charles C. Miller,[c] McGovern Medical School at UT Houston and Memorial Hermann Hospital, Houston, Tex; [b]Memorial Hermann Hospital, Houston, Tex; [c]University of Texas Health Science Center, Houston, Tex

Patients: 1,143
Years: 2017-2020

	No. (%)	CVA/TIA	Cost
CEA	798 (69.8)	1.1%	$7,787
TFCAS	168 (14.7%)	4.2%	$12,528
TCAR	177 (15.5%)	1.7%	$14,125
		p < .03	*p* < .05

U Tex Houston, Hermann Memorial Hosp. Houston

J Vasc Surg, 2021

TCAR: *Cost*

Carotid endarterectomy remains cost-effective for the surgical management of carotid stenosis

Natalie D. Sridharan, MD, MS,[a] Rabih A. Chaer, MD, MS,[a] Kenneth Smith, MD, MS,[b] *and* Mohammad H. Eslami, MD,[a] *Pittsburgh, Pa*

				Symptomatic subgroup		
	Total cost, $	Total QALY	ICER, $/QALY	Total cost, $	Total QALY	ICER, $/QALY
CEA	228,933	9.79	–	226,781	9.64	–
TCAR	233,763	9.82	+160,642	233,042	9.68	+140,393
TFCAS	234,373	9.80	Dominated	234828	9.62	Dominated

CEA, Carotid endarterectomy; *ICER*, incremental cost-effectiveness ratio; *QALY*, quality-adjusted life-year; *TCAR*, transcarotid artery revascularization; *TFCAS*, transfemoral carotid artery stenting.

CONCLUSIONS

TCAR does not meet a traditional cost-effectiveness threshold to replace CEA as the primary treatment modality for carotid stenosis. TFCAS is the least cost-effective strategy for carotid revascularization.

J Vasc Surg, 2022

SVS Society for Vascular Surgery

CLINICAL PRACTICE GUIDELINES

Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease

the data at present are inadequate to make a recommendation on the role of TCAR

J Vasc Surg, 2022

J Vasc Surg, 2022

CONCLUSION

DR. ALFRED BLALOCK:

" It usually requires a considerable time

Is it Time for a Randomized Clinical Trial ?

longer still to ascertain its harmful effects "