TCAR Should Be The Default Procedure for Carotid Revascularization

39th Annual Meeting of the Florida Vascular Society
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Disclosures

Nothing to disclose

Carotid Revascularization

- Carotid Endarterectomy has traditionally been the gold-standard
  - Despite considerable experience, the risk of major complications persists
    - Periprocedural stroke
    - Cranial Nerve Injury
    - Myocardial Infarction
- Transfemoral carotid stenting was initially presented as a less invasive alternative to CEA.
  - Noninferior to CEA
  - Major shortcoming – increased perioperative strokes
- Opportunity for introduction of TCAR
  - Hybrid procedure
    - Obviating aortic arch manipulation
    - Establish embolic protection prior to lesion crossing

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 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. CREST. NEJM 2010.

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Initial TCAR Experience

- Industry-
  prospect
  TCAR
  - Compare
    feasibil
    - P
    - R
    - R

Context of these data:

1. All patients were considered high-risk anatomically or physiologically
2. Operators had, at most, an experience of five cases prior to participating in the trial

Favorable reduction in perioperative stroke, relative to historical studies

	CREST 1	CREST 2		TCAR (PP)
CEA	2.3%	3.7%	vs.	0.70%
TFCAS	4.1%	2.8%		

ticenter trial of
ic flow reversal

MD,[c] L. Nelson Hopkins, MD,[d]
MD,[g] and Richard P. Cambria, MD,[a]
Sunnyvale, Calif

major
treat (*ITT*)

ITT population (N = 141)
5 (3.5) 1.16-8.08 .0047
2 (1.4) 2 (1.4) 1 (0.7)

CI, Confidence interval; *MI,* myocardial infarction.
[a]Defined as stroke, death, myocardial infarction.

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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

CEA, Carotid endarterectomy; *CI*, confidence interval; *CMS*, Centers for Medicare & Medicaid Services; *MI*, myocardial infarction; *OR*, odds ratio; *TCAR*, transcarotid artery revascularization; *TFCAS*, transfemoral carotid artery stenting.

[a]Adjusted for age, race, smoking status, diabetes, hypertension, and statin use.

[b]Adjusted for age, sex, race, smoking status, congestive heart failure stage I/II, and statin use.

[c]Adjusted for age, race, smoking status, diabetes, and statin use.

[d]Adjusted for age, sex, smoking status, coronary artery disease, and congestive heart failure stage I/II.

Zhang, et al. 2022 JVS.

TCAR outcomes are excellent in the standard surgical risk population

- ROADSTER 3
  - Prospective, single arm, multicenter post-approval study
  - Standard Surgical Risk Patients
    - Per-protocol n=320
    - Primary end-point
      - Stroke/death/MI within 30 days

TABLE 4. Stroke, Death, Myocardial Infarction, and Cranial Nerve Injury within 30 Days

	ITT (N = 344)	PP (N = 320)
Stroke/death/MI	0.9% (3/343)	0.6% (2/320)
Stroke	0.9% (3/343)	0.6% (2/320)
Death	0.0% (0/343)	0.0% (0/320)
MI	0.0% (0/343)	0.0% (0/320)
Cranial nerve injury	0.6% (2/343)	0.6% (2/320)

The denominator for 30-day events includes patients with events and those without events who were followed for at least 23 days.
ITT = intention to treat; PP = per protocol; MI = myocardial infarction.

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Jim, et al. Ann Neurol 2026;99:705-712

Table III. Relationship between approach and adverse outcomes among Centers for Medicare & Medicaid Services (CMS) standard-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	1.55 (1.33-1.80)	<.001	1.60 (1.37-1.86)	<.001
TCAR	1.06 (0.85-1.32)	.626	1.05 (0.84-1.31)	.659
Death[b]				
Approach				
CEA	Ref		Ref	
TFCAS	3.18 (2.36-4.29)	<.001	3.35 (2.47-4.54)	<.001
TCAR	1.62 (1.00-2.63)	.049	1.58 (0.97-2.56)	.066
Stroke/death[c]				
Approach				
CEA	Ref		Ref	
TFCAS	1.71 (1.49-1.97)	<.001	1.77 (1.54-2.04)	<.001
TCAR	1.12 (0.91-1.37)	.287	1.11 (0.91-1.37)	.302
MI[d]				
Approach				
CEA	Ref		Ref	
TFCAS	0.62 (0.43-0.90)	.012	0.61 (0.49-0.77)	<.001
TCAR	0.90 (0.61-1.33)	.607	0.68 (0.55-0.85)	.001

CEA, Carotid endarterectomy; *CI*, confidence interval; *MI*, myocardial infarction; *OR*, odds ratio; *TCAR*, transcarotid artery revascularization; *TFCAS*, transfemoral carotid artery stenting.

[a]Adjusted for age, race, hypertension, diabetes, and statin use.

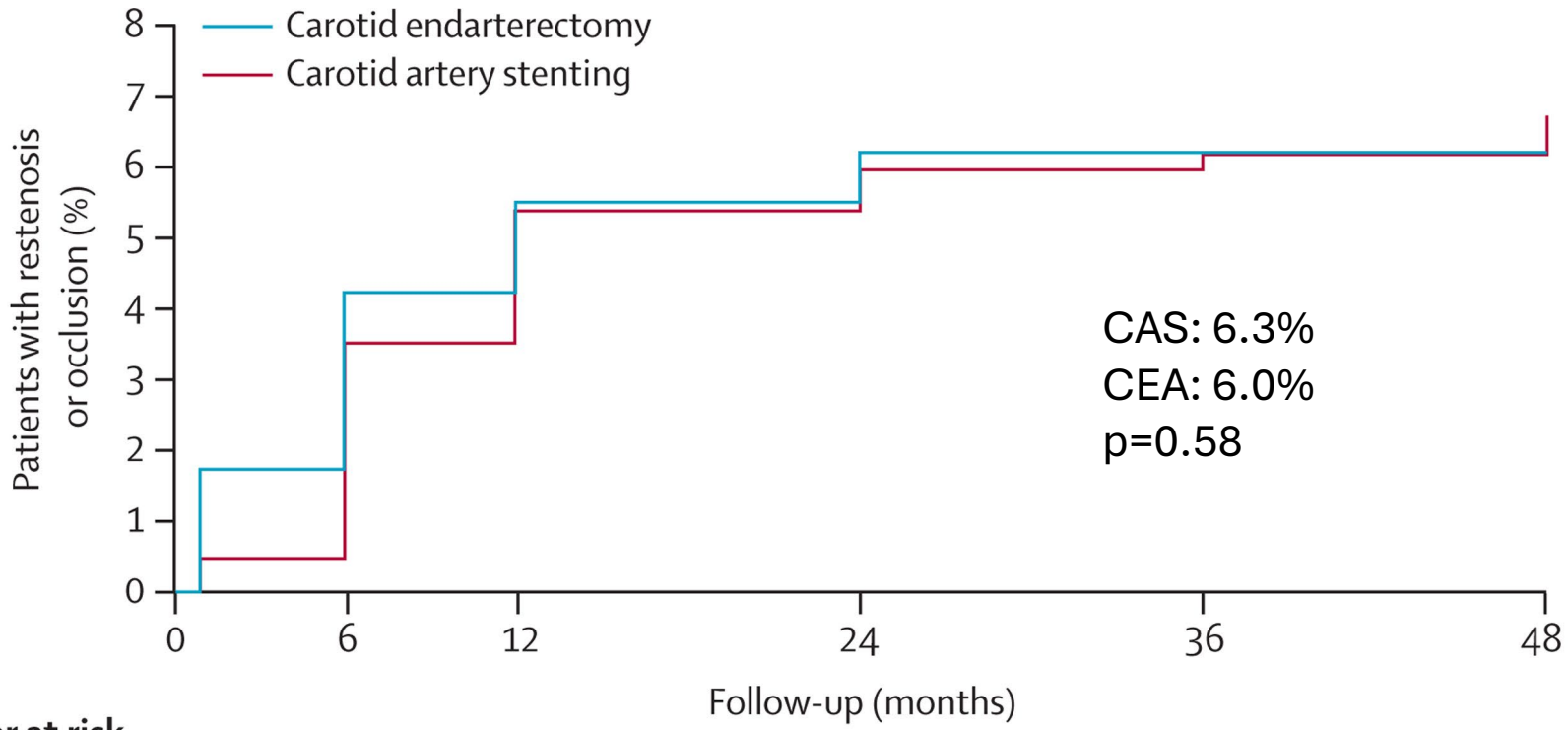
[b]Adjusted for age, congestive heart failure stage I/II, and statin use.

[c]Adjusted for age, race, hypertension, diabetes, and statin use.

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

Zhang, et al. 2022 JVS.

Durability of Carotid Stenting

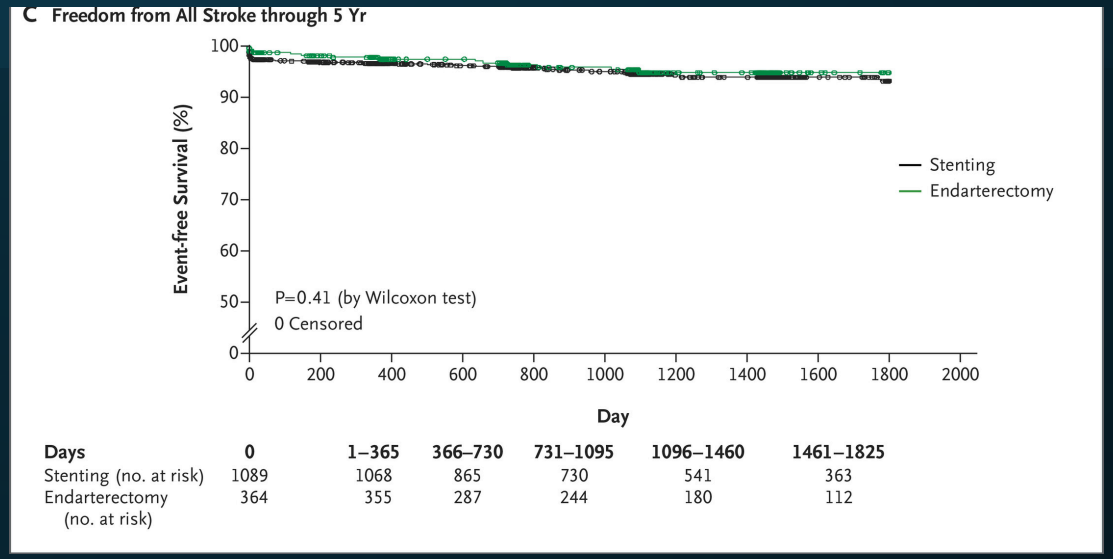


Number at risk

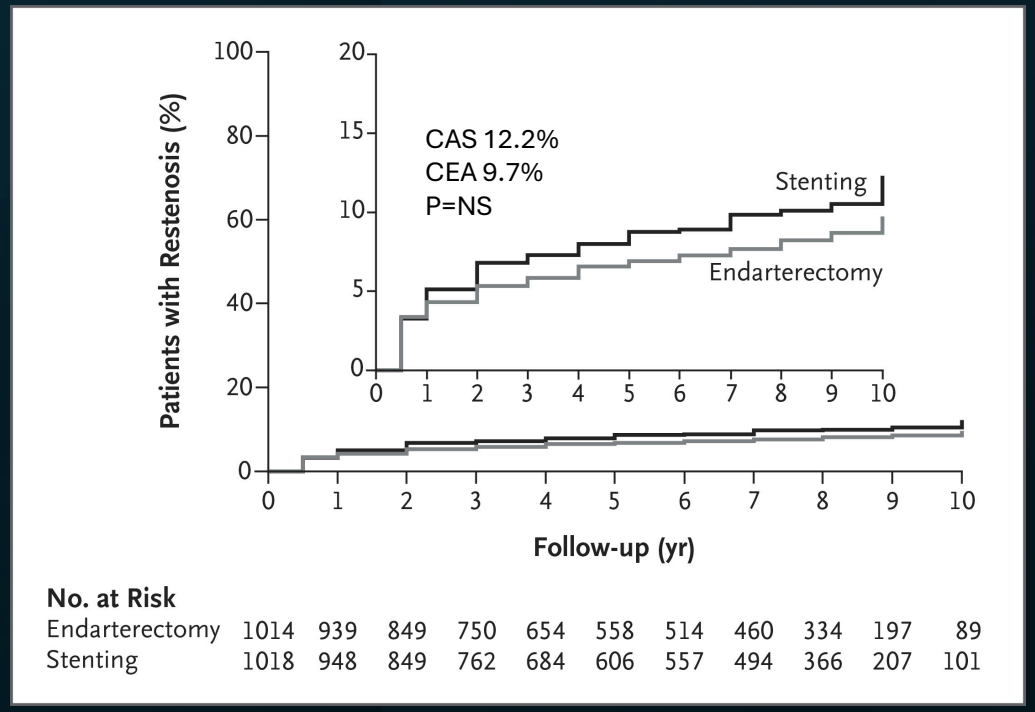
Carotid artery stenting	1087	1014	921	674	399	172
Carotid endarterectomy	1107	1016	919	652	392	163

Lal, et al. Lancet Neurology 2012.

Durability of Carotid Stenting



Rosenfeld, et al. NEJM 2016



Brott, et al. NEJM 2016

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Conclusions

Real world clinical data have demonstrated that TCAR achieves the lowest incidence of periprocedural stroke, compared to CEA and TFCAS, in ‘high surgical risk’ patients.

For standard surgical risk patients, TCAR appears to provide at least equivalent outcomes, compared to CEA, and less periprocedural strokes compared to TFCAS.

Ultimately, patient selection, with special considerations for lesion morphology, anatomy, and medical compliance remain paramount to achieve these reported outcomes.

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Thank you