TCAR Is Safe In Recently Symptomatic Patients And Those With Contralateral Carotid Occlusions: Why It Should Be The Procedure Of Choice In Those Conditions

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Peter A. Schneider Disclosures

Consulting:

Surmodics, Medtronic, Boston Scientific, Phillips, Cagent, Acotec, Abbott, Endologix, Shockwave, Silk Road, Healthcare Inroads, Inari, BD

Carotid Repair in Patients With Contralateral Carotid Artery Occlusion

- Higher burden of atherosclerosis
- More CAD
- Hemodynamic instability is more risky
- Both hemispheres at risk
- Increased in-hospital stroke risk with CEA – 4.2% with CCO vs 2.5% without
 - 3.7% with CCO vs 2.2% without (symptomatic)

Menyhei et al. Eur J Vasc Endovasc Surg 2011;41:735 Rockman et al. J Vasc Surg 2002;36:668

TCAR vs CEA in Contralateral	Carotid	Occlusion
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		Univ	ariable	analy	sis	s Multivariable analysis		sis		
Outcomes	С	CEA		AR	TCAR vs CEA (reference)				Hosmer- Lemeshow	
	n	%	n	%	p Value	OR (95% CI)	p Value	C- statistic	p Value	
Stroke or death*	70	2.8	17	1.5	0.02	0.57 (0.29-1.10)	0.10	0.71	0.51	
Stroke, death, or MI	85	3.4	21	1.8	0.01	0.52 (0.28-0.94)	0.03	0.72	0.18	
Stroke	60	2.4	17	1.5	0.10	0.65 (0.33-1.28)	0.21	0.70	0.18	
Death	19	0.75	6	0.5	0.44	0.78 (0.27-2.27)	0.65	0.81	0.75	
MI	18	0.7	5	0.4	0.33	0.45 (0.17-1.18)	0.10	0.86	0.77	
					Stroke/	death.				
					CEA	2.8%				
					TCAR	1.5%				

Asymptomatic	Outcomes		CI (n = 2		TC. (n =			TCAR vs	CEA
			n	%	n	%	p Valu	e OR (95% CI	p Valu
	Stroke or death		51	2.5	10	1.1	0.01	0.44 (0.21-0.95)	0.04
	Stroke, death, or M	MI	62	3.0	13	1.4	0.01	0.41 (0.21-0.82)	0.01
	Stroke		47	2.3	10	1.1	0.02	0.46 (0.21- 0.97)	0.04
				TO	CAR		-		
Symptomatic	Outcomes		CEA = 464		1 = 07)		- 2	TCAR vs C	EA
Symptomatic	Outcomes					p Val		TCAR vs C OR (95% CI)	EA P Value
Symptomatic	Outcomes Stroke or death	(n	= 464) 2	07)		ue		р
Symptomatic		(n n	= 464 %) 2 n 7	07) %	Va	iue 56 (OR (95% CI)	p Value

TCAR in	Contralateral Ca	rotid Occlusion	
	No CCO (n = 4892 [89.2%]), No. (%)	CCO (n = 593 [10.8%]), No. (%)	P value
In-hospital outcomes			
Ipsilateral stroke	53 (1.1)	6 (1.0)	.87
Contralateral stroke	8 (0.2)	5 (0.8)	.001
Stroke	59 (1.2)	10 (1.7)	.32
TIA	34 (0.70)	6 (1.0)	.39
Death	18 (0.37)	4 (0.67)	.27
MI	24 (0.49)	3 (0.51)	.96
Reperfusion syndrome	20 (0.41)	3 (0.51)	.73
Stroke/TIA	91 (1.9)	16 (2.7)	.17
Stroke/death	71 (1.5)	10 (1.7)	.65
Stroke/death/MI	89 (1.8)	13 (2.2)	.53
30-day outcomes			
Mortality	31 (0.6)	5 (0.8)	.55
Available follow-up*	11,227 (25.1)	132 (22.3)	.13
Stroke	14 (1.5)	2 (2.0)	66
Stroke/death	16 (1.3)	2 (1.5)	.69
Stroke/death/MI	22 (1.8)	3 (2.3)	.73
	rates with TCAR about lateral occlusion is pres		

Dakour-Aridi et al. J Vasc Surg 2021;73:524

Carotid Repair: Recently Symptomatic Patients

- Unstable plaque
- Early CEA appears to be relatively safe
 - Very early CEA may have higher risk of perioperative stroke and death.
 - Swedevasc: <2d=11.5%, 3-14d=3.6-4.0%, >15d=5.4%

CLINICAL PRACTICE GUIDELINES Society for Vascular Surgery clinical practice guidelines for management of extracranial cerebrovascular disease 31. In patients with recent stable stroke (modified Rankin scale score 0-2), we recommend carotid revascularization for symptomatic patients with >50% stenosis to be performed as soon as the patient is neurologically stable after 48 hours but definitely before 14 days after the onset of symptoms. Level of recommendation: grade 1 (strong): quality of evidence: B (moderate).

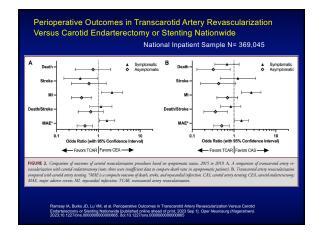
y of evi-Savardekar et al. Neurosurgery 2019:85:E214 Stromberg et al. Stroke 2012;43:1331. AbuRahma et al. J Vasc Surg 2022;75:45

TCAR in Recently Symptomatic <2days 3-14 days 15-180 days N=144 (5.2%) N=928 N=1536 (35.6%) (58.9%) P value vs P value vs ≥15d ≥15d Stroke 5.6% 0.01 2.5% 0.40 2.0% Death 1.4% 0.17 1.0% 0.27 0.5% 6.5% 2.9% 0.48 2.3% Stroke/death 0.01 In-hospital outcomes Acceptable risk of stroke/death at 3-14 days after stroke presentation Cui et al. J Vasc Surg 2021;73:1649

0.1.1.1.1.1.1		Interval to surgery		
Cui et al. J Vasc Surg 2021;73:164 Variable	9 0-2 Days (n = 144; 5.52%)	3-14 Days (n = 928; 35.58%)	15-180 Days (n = 1536; 58.9%)	Pvalu
Demographics				
Female sex	54 (37.5)	351 (37.8)	544 (35.4)	.47
Age, years	72.6 ± 10.1	73.2 ± 10.4	72.8 ± 9.8	.62
Nonwhite race	12 (8.3)	128 (13.8)	142 (93)	<.01
Hispanic ethnicity	4 (2.8)	35 (3.8)	62 (4.1)	.74
BMI, kg/m²	29.9 ± 6.0	28.3 ± 6.0	28.7 ± 8.1	.63
Comorbidities				
Diabetes	57 (39.6)	362 (39.0)	612 (39.8)	.92
Hypertension	128 (88.9)	838 (90.3)	1397 (91.0)	.64
Congestive heart failure	25 (17.4)	168 (18.1)	258 (16.8)	.71
Coronary artery disease	56 (38.9)	388 (41.8)	713 (46.4)	.03
History of CABG or PCI	44 (30.8)	302 (32.5)	543 (35.4)	.25
COPD	22 (17.2)	222 (26.9)	456 (32.8)	<.001
Current smoker	65 (45.1)	397 (42.8)	794 (51.8)	<.001
GFR <60 mL/min/1.73 m ²	82 (57.8)	508 (55.8)	910 (60.6)	.07
Dialysis	2 (1.4)	15 (1.6)	26 (1.7)	.96
Previous ipsilateral CAS/CEA	12 (8.3)	84 (9.1)	160 (10.4)	.45
Preoperative hemoglobin, g/dL	13.0 ± 2.1	13.0 ± 2.1	13.1 ± 1.9	.05
Preoperative medication				
Aspirin	127 (88.2)	833 (89.9)	1417 (92.3)	.06
β-Blocker	76 (52.8)	498 (53.7)	856 (55.7)	.53
Statin	118 (81.9)	833 (89.8)	1402 (91.3)	<.01
P2Y12 inhibitor	107 (74.3)	780 (84.1)	1386 (90.2)	<.001
ACE Inhibitor	68 (47.2)	445 (48.0)	791 (51.5)	.18
Stroke presentation	71 (49.3)	528 (56.9)	779 (50.7)	.01
Stenosis >80%	63 (45.0)	391 (42.4)	679 (44.6)	.55
General anesthesia	117 (81.2)	709 (76.5)	1254 (81.6)	<.01

	CEA	TCAR	Adjusted OR	
<u><</u> 2d	4.0	6.5	1.9 (0.9-4.0)	NS
3-14d	2.5	2.9	1.1 (0.7-1.7)	NS
>14d	1.6	2.3	1.5 (0.9-2.3)	NS
Odds Ratio >1.0) Favors CEA	Symptomati OR (95% CI)	P- value	
Death		0.75 (0.37-1.53)		
Stroke MI		0.96 (0.66-1.39)	0.01	
Stroke/Death		0.86 (0.60-1.23)	TCAR (n=5716) vs C	
Stroke/Death/N	41	0.70 (0.50-0.98)		2020

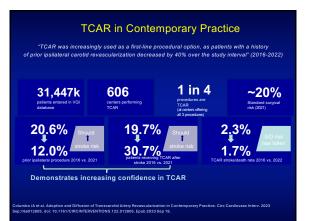
ROADSTER 2 Trial: 602 TCAR patients-Post Market Study							
	Asympto			ptomatic		9 ≥ 80	
	n=467 n=165		n=134				
Stroke/Death/MI	9	1.9%	2	1.2%	4	3.0%	
Stroke	3	0.6%	1	0.6%	2	1.5%	
Death	1	0.2%	0	0.0%	0	0.0%	
MI	5	1.1%	1	0.6%	2	1.5%	
Stroke/Death	4	0.9%	1	0.6%	2	1.5%	
Enrollment by new			Strok	atus and Age		2020 Sep;51(9)-2	620-2629
Enrollment by new operators: 70% Enrollment at site new to TCAR: 80%				Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patient With Significant Carotid Artery Disease			
			Hans-Hen Douglas M Mahmoud	Kashyap [®] , MD; Peter A. Schneider, MD; ning Eckstein, MD; Steve Henac, MD; G tassop [®] , MD; Toć Hanner, MD; Jessico B. Malac, MD; Facek R. Acka III, MD; Da of the RG4DSTER 2 Investigators'	lenn LaMuraglia, MD; I Titus, MD; Wesley S I	Michael C. Stone; MD; Jim M Noone, MD; Rublin Rodriguez	elton, DO; -Carvajal, MD;



Outcome*	Transcarotid Artery Revascularization ⁹ (n = 1829)	rransfemoral Carotid Artery Stenting ^b (n = 1829)	Absolute Difference	Relative Risk (95% CI)	P Value
Stroke or death	39 (2.1)	76 (4.2)	-2.02 (-3.21 to -0.83)	0.51 (0.35 to 0.75)	<.001
Stroke or death, 30 d	47 (2.6)	88 (4.8)	-2.22 (-3.53 to -0.96)	0.53 (0.38 to 0.76)	<.001
Stroke	36 (2.0)	56 (3.1)	-1.10 (-2.17 to -0.02)	0.64 (0.42 to 0.97)	.04
Stroke, 30 d	36 (2.0)	58 (3.2)	-1.20 (-2.29 to -0.12)	0.62 (0.41 to 0.94)	.02
Transient ischemic attack	14 (0.8)	25 (1.4)	-0.60 (-1.33 to 0.12)	0.56 (0.29 to 1.08)	.08
Death	9 (0.5)	28 (1.5)	-1.04 (-1.74 to -0.33)	0.32 (0.15 to 0.68)	.002
Death, 30 d	17 (0.9)	39 (2.1)	-1.20 (-2.06 to -0.35)	0.44 (0.25 to 0.77)	.003
Myocardial infarction	1(0.1)	6 (0.3)	-0.27 (-0.61 to 0.06)	0.17 (0.02 to 1.38)	.06
Heart failure exacerbation	11 (0.6)	17 (0.9)	-0.33 (-0.95 to 0.29)	0.65 (0.30 to 1.38)	.26
Access site bleeding complication	74 (4.0)	74 (4.1)	-0.05 (-1.40 to 1.29)	0.99 (0.72 to 1.36)	.93
	74 (4.0)	74(4.1)	-003(-14010123)	0.55 (0.72 (0.1.30)	.93

Patients Undergoing TCAR							
Symptomatic Patients	N=31						
Symptom timing	Mean 29 days (range 5-55d)						
Reversed flow time	12.1 min.						
Procedure time	64.4 min.						
Local anesthesia	61.3%						
Stroke/death	0						
New DW-MRI lesions	35.5% at 48h. 15.4% at 30d						
Volume new lesions	0.22ml at 48h. 0.11ml at 30d						

Site Name	PI	Location	Subjects Enrolled
Complejo Hospitalario de Toledo	Dr. Jose Ignacio Leal Lorenzo	Toledo, Spain	10
Universitair Ziekenhuis Gent	Dr. Isabelle Van Herzeele	Ghent, Belgium	10
Technical University Munich	Prof. Dr. Hans-Henning Eckstein	Munich, Germany	11



TCAR Is Safe In Recently Symptomatic Patients And Those With Contralateral Carotid Occlusions **Conclusion**

- TCAR: competitive with CEA.
- Prospective studies with neurological control, independent adjudication show safety and efficacy.
- This is now extending to multiple specific subgroups, including; patients with recent symptoms and those with contralateral occlusion.

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