Latest Data on TCAR

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Disclosure

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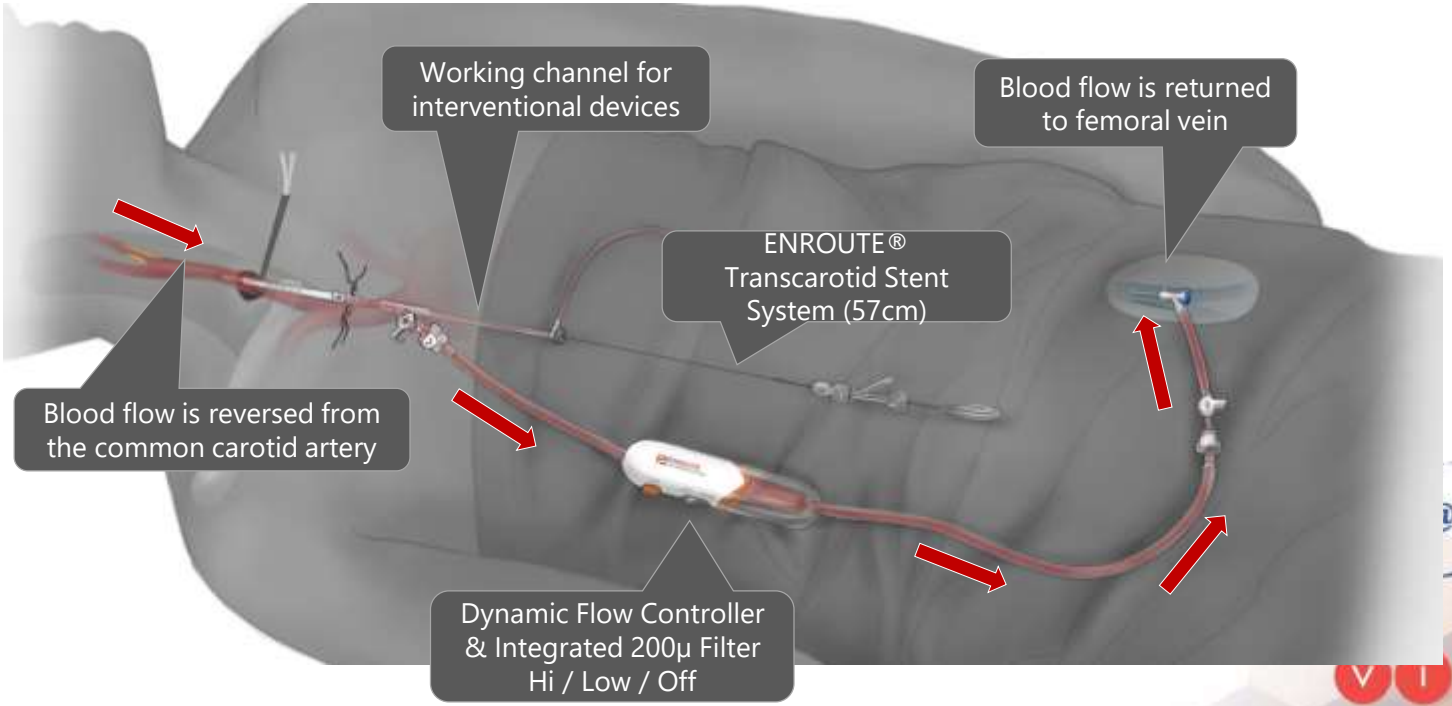
I have the following potential conflicts of interest to report:

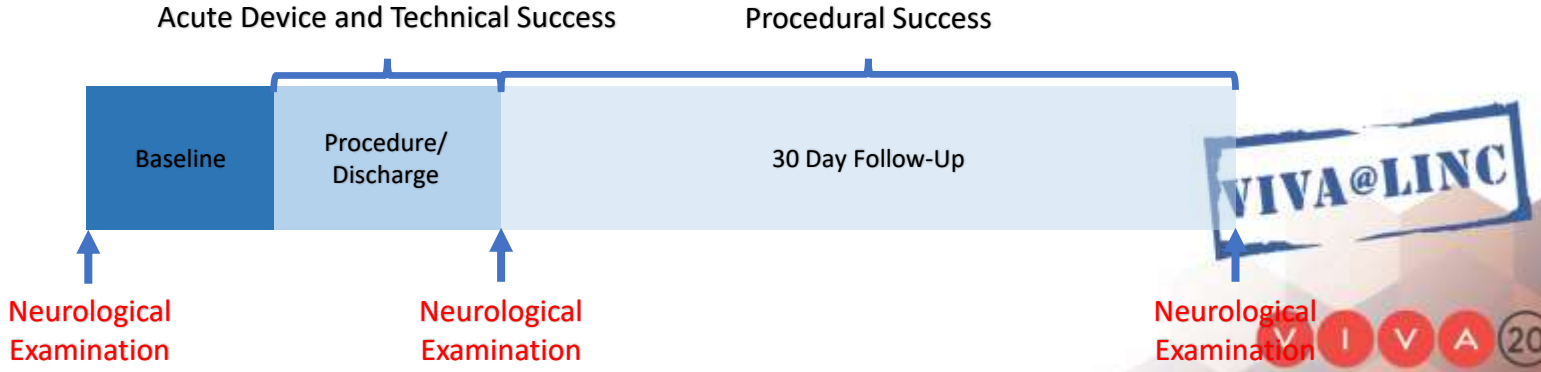
Consulting: Philips, Medtronic, Boston Scientific, Intact, PQ Bypass, Cagent, Silk Road Medical, Surmodics, Profusa, CSI

TransCarotid Artery Revascularization: TCAR



ROADSTER 2: Study Design

- **FDA-Mandated Post Approval Study** (condition of FDA approval for the ENROUTE Transcarotid Stent System)
- **Minimum of 600 patients treated Per-Protocol** (all subjects enrolled without a major protocol deviation)
- **70% new sites**, no more than 30% ROADSTER 1 sites
- **Independent adjudication** of major adverse events
- **Dedicated TCAR System** = ENROUTE NPS + ENROUTE Stent
- **Objective:** The ROADSTER 2 Study is intended to evaluate **real world usage** of the ENROUTE Transcarotid Stent when used with the ENROUTE Transcarotid Neuroprotection System.



ROADSTER 2: Procedure Information

Parameter	ROADSTER 1 n=219	ROADSTER 2 n=632
ROADSTER 1 Operators	100%	20.0%
Enrollment by New Operators	65.3%	70.0%
Skin-to-Skin Time (median)	70 mins	75 mins
Reverse Flow/Clamp Time (median)	9 mins	11 mins
Fluoro Time (median)	N/R	5.0 mins
Contrast Usage (median)	62 cc	36 cc

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Presented by V Kashyap, VAM June 2019

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ROADSTER 2: Procedure Information

Parameter	ROADSTER 1 n=219	ROADSTER 2 n=632	*p*-value
General Anesthesia	59.6%	71.7%	P<0.001
Local Anesthesia	47.0%	24.7%	P<0.001
Regional Block	0.0%	3.6%	0.042
Tolerance to High Flow	98.6%	98.0%	1.00
Tolerance to Low Flow	100%	100%	1.00
Local Complications			
Bleeding at Arteriotomy	0.0%	0.0%	1.00
Hematoma (requiring intervention)	2.3%	0.0%	0.0013
CCA Dissection (requiring surgical repair)	1.8%	0.8%	0.14
Cranial Nerve Injury	0.5%	1.3%	0.30
Permanent	0.0%	0.5%	1.00

ROADSTER Trials:

Comparative Clinical Outcomes

FDA Analysis Population

	ROADSTER 1 n=203		ROADSTER 2 n=632		*p*-value
Stroke/Death/MI	6	3.0%	11	1.7%	0.40
Stroke	1	0.5%	4	0.6%	1.00
Death	2	1.0%	1	0.2%	0.15
MI	3	1.5%	6	0.9%	0.46
Stroke/Death	3	1.5%	5	0.8%	0.46
Neurological Death	0	0.0%	0	0.0%	1.00
Cardiac Death	1	0.5%	0	0.0%	0.24

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ROADSTER Trials:
Comparative Outcomes by Symptom Status

Asymptomatic Patients – FDA Analysis Population

	ROADSTER 1 n=157		ROADSTER 2 n=467		*p*-value
Stroke/Death/MI	4	2.5%	9	1.9%	0.7587
Stroke	1	0.6%	3	0.9%	1.0000
Death	1	0.6%	1	0.2%	0.4402
MI	2	1.3%	5	1.1%	1.0000
Stroke/Death	2	1.3%	4	0.9%	1.0000

Symptomatic Patients – FDA Analysis Population

	ROADSTER 1 n=46		ROADSTER 2 n=165		*p*-value
Stroke/Death/MI	1	2.2%	2	1.2%	0.5237
Stroke	0	0.0%	1	0.6%	1.0000
Death	1	2.2%	0	0.0%	0.2180
MI	0	0.0%	1	0.6%	1.0000
Stroke/Death	1	2.2%	1	0.6%	0.3893

SVS | VQI
VASCULAR QUALITY INITIATIVE

Objectives:
TCAR Surveillance Project (TSP)

- Monitor the safety and effectiveness of stents placed directly into the carotid artery while reversing blood flow within the carotid artery to reduce stroke risk.

- Compare this less-invasive surgical procedure with standard carotid endarterectomy in centers that participate in the Society for Vascular Surgery Vascular Quality Initiative.

Provide "**REAL-WORLD**" Outcomes

Presented by M Malas at VAM June 2019

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Baseline Characteristics

	CEA (N=44,442)	TCAR (N=5,716)	P-value	Standardized Difference*
Median Age, IQR	71 (65-77)	74 (67-80)	**<0.001**	-0.27
Age ≥75 years	16,023 (36.1)	2,796 (48.9)	**<0.001**	-0.26
Female Gender	17,508 (39.4)	2,082 (36.4)	**<0.001**	0.06
Non-White Race	4,513 (10.2)	559 (9.8)	0.38	0.01
Symptomatic Status	13,151 (29.6)	2,207 (38.6)	**<0.001**	0.19
HTN	39,766 (89.5)	5,194 (90.9)	**<0.01**	0.05
DM	16,313 (36.7)	2,175 (38.0)	0.05	0.03
CAD	11,874 (26.7)	2,960 (51.8)	**<0.001**	0.53
Prior CABG/PCI	15,316 (34.5)	2,327 (40.7)	**<0.001**	0.13
CHF	4,945 (11.1)	1,076 (18.8)	**<0.001**	0.22
COPD	10,292 (23.2)	1,585 (27.7)	**<0.001**	0.10
CKD	14,597 (33.4)	2,180 (39.0)	**<0.001**	0.11
Dialysis	434 (1.0)	93 (1.6)	**<0.001**	0.06
Prior Ipsilateral CEA	758 (1.7)	937 (16.4)	**<0.001**	0.53
Prior Ipsilateral CAS	110 (0.25)	83 (1.5)	**<0.001**	0.13
Ipsilateral Stenosis >= 80%	20,521 (47.0)	2,999 (54.2)	**<0.001**	0.14

**Some have proposed that an absolute standardized difference of 0.10 or more indicates that covariates are imbalanced between groups*

Baseline Characteristics (cont'd)

	CEA (N=44,442)	TCAR (N=5,716)	P-value	Standardized Difference*
Contralateral CEA/CAS	6,057 (13.6)	994 (17.4)	**<0.001**	**0.10**
Contralateral Occlusion	1,812 (4.3)	593 (10.8)	**<0.001**	**0.25**
Anatomic High-Risk	1,838 (4.1)	2,812 (49.2)	**<0.001**	**1.18**
Radiation History	576 (1.3)	328 (11.8)	**<0.001**	**-0.43**
Preoperative Medications				
Aspirin	37,414 (84.2)	5,097 (89.2)	**<0.001**	**0.15**
Statin	37,363 (84.1)	5,064 (88.6)	**<0.001**	**0.13**
P2Y12-Receptor Antagonists	15,712 (35.4)	4,945 (86.5)	**<0.001**	**1.23**
Beta Blockers	23,965 (54.0)	3,297 (57.7)	**<0.001**	0.08
Anticoagulation	4,779 (10.8)	819 (14.3)	**<0.001**	**0.11**
ACE Inhibitors	23,623 (53.2)	3,081 (53.9)	0.29	0.01
ASA Class IV-V	9,151 (20.6)	1,660 (29.1)	**<0.001**	**0.20**
Elective procedures	39,036 (87.9)	5,139 (89.9)	**<0.001**	0.06
General Anesthesia	41,124 (92.6)	4,664 (81.6)	**<0.001**	**0.33**

**Some have proposed that an absolute standardized difference of 0.10 or more indicates that covariates are imbalanced between groups*

Univariable Analysis

	CEA	TCAR	P-value
In-Hospital Outcomes			
Death	152 (0.3)	19 (0.5)	**0.03**
Ipsilateral Stroke	504 (0.9)	48 (1.2)	0.10
Stroke	677 (1.2)	57 (1.4)	0.37
MI	391 (0.7)	19 (0.5)	0.07
Stroke/Death	773 (1.4)	67 (1.6)	0.23
Stroke/Death/MI	1,119 (2.0)	83 (2.0)	0.98
Cranial Nerve Injury	1,463 (2.6)	9 (0.3)	**<0.001**
Post-procedural Hypotension	5,568 (10.1)	605 (14.7)	**<0.001**
Post-procedural Hypertension	10,983 (19.9)	575 (14.0)	**<0.001**
Bleeding with intervention	578 (1.0)	53 (1.3)	0.14
LOS more than 1 day	17,290 (31.2)	1,220 (29.6)	**0.03**
Non-Home Discharge	3,543 (6.4)	270 (6.6)	0.70

Multivariable Logistic Regression

<1.0 favors TCAR, >1.0 favors CEA	TCAR vs. CEA	
	OR (95% CI)	*P-value*
In-hospital Outcomes		
Death	0.94 (0.57-1.53)	0.80
Ipsilateral Stroke	0.99 (0.72-1.39)	0.99
Stroke	0.89 (0.66-1.19)	0.43
MI	0.46 (0.30-0.72)	<0.01
Stroke/Death	0.85 (0.65-1.13)	0.27
Stroke/Death/MI	0.69 (0.54-0.89)	<0.01
Cranial Nerve Injury	0.12 (0.07-0.19)	<0.001
Post-procedural Hypotension	1.59 (1.30-1.94)	<0.001
Post-procedural Hypertension	0.58 (0.48-0.71)	<0.001
Bleeding with intervention	1.12 (0.84-1.50)	0.44
Non-Home discharge	0.73 (0.61-0.88)	<0.01
Hospital Stay for more than 1 day	0.74 (0.64-0.84)	<0.001

*Adjusted for symptomatic status, age, CAD, CHF, COPD, CKD, prior ipsilateral CEA, prior ipsilateral CAS, Contralateral occlusion, ASA Class and statin use

In-Hospital Outcomes based on Symptomatic Status CEA vs TCAR

<1.0 favors TCAR >1.0 favors CEA	Asymptomatic		Symptomatic	
	OR (95% CI)	P-value	OR (95% CI)	P-value
Death	1.14 (0.57-2.31)	0.71	0.75 (0.37-1.53)	0.43
Stroke	0.79 (0.51-1.24)	0.31	0.96 (0.66-1.39)	0.84
MI	0.51 (0.29-0.91)	0.02	0.39 (0.20-0.76)	0.01
Stroke/Death	0.85 (0.57-1.26)	0.41	0.86 (0.60-1.23)	0.42
Stroke/Death/MI	0.69 (0.49-0.95)	0.02	0.70 (0.50-0.98)	0.04

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CEA vs TCAR: 30-day Outcomes

	Unadjusted			Adjusted		
	CEA	TCAR	P-value	CEA	TCAR	P-value
Mortality	308 (0.70)	40 (0.70)	0.95	Ref.	0.66 (0.46-0.95)	0.03
Stroke	241 (1.4)	16 (1.1)	0.46	Ref.	0.68 (0.39-1.20)	0.18
MI	140 (0.80)	9 (0.6)	0.52	Ref.	0.36 (0.16-0.83)	**0.02**
Stroke/Death	323 (1.8)	19 (1.4)	0.19	Ref.	0.54 (0.33-0.89)	**0.02**
Stroke/Death/MI	453 (2.6)	27 (1.9)	0.13	Ref.	0.47 (0.30-0.74)	**<0.01**

*Adjusted for age, symptomatic, CAD, CHF, COPD, CHF, CKD, prior ipsilateral CEA or CAS, contralateral occlusion, ASA Class

TCAR Patient Population

ONE risk factor qualifies patient for CMS high surgical risk status

- **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

- **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

~2/3 of carotid revascularization patients qualify as a CMS High Surgical risk status.

These criteria are considered reimbursement eligible for the TCAR Procedure per the Medicare National Coverage Determination (20.7) on PTA including CAS.

https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=201

List is a compendium of all risk factors across all carotid stent and EPD IDE trials.

Latest Data on TCAR

Conclusion

- Latest data suggests that results of TCAR are similar to CEA
  - Major endpoints
  - Properly selected patients
  - Data on TCAR is in patients at high risk for CEA

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NOVEMBER 2-5, 2020

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THE VEINS AT VIVA

OCTOBER 31-NOVEMBER 2, 2020

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Latest Data on TCAR

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