FAVORABLE 30-DAY RESULTS OF TCAR IN GOOD RISK SYMPTOMATIC AND ASYMPTOMATIC PATIENTS: RESULTS FROM ROADSTER-3

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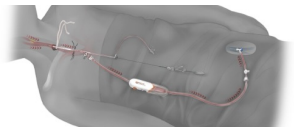
Disclosures

- Co-PI on ROADSTER 3 Trial

Background

- TCAR has been performed on over 100,000 patients in the US since 2015
- ROADSTER & ROADSTER 2 established the safety and effectiveness of TCAR in High-Risk patients
- ROADSTER 3 launched to evaluate TCAR in the Standard Surgical Risk population



ROADSTER 3 Post-Approval Study

Study Design	Prospective, multi-center, single arm, **FDA-required post-approval study**
Enrollment / Sites	**344 ITT** **320 PP** 53 sites all in the USA
Enrollment Period	September 2022 - June 2024
Primary Endpoint	Composite of 30-day S/D/MI and 1-year ipsilateral stroke
Key Secondary Endpoints	30 days: • CNI • S, D, MI 1 year: • Ipsilateral stroke
Patient Population	Patients at **standard surgical risk** and eligible for TCAR • **Symptomatic:** ≥70% stenosis by ultrasound or ≥50% stenosis by CTA • **Asymptomatic:** ≥70% stenosis by ultrasound or ≥60% stenosis by CTA
Follow-up Visits	Within 24hrs 30 Days 6 Months* 1 Year

*Required only for patients with suspected CNI at 30 days

Study Details

Key Study Features

- Event adjudication by independent CEC

Independent neurological assessments

- No lead-in period
- DAPT + Statin medications
  - Pre-procedure
  - 30-days Post-procedure

Study Status

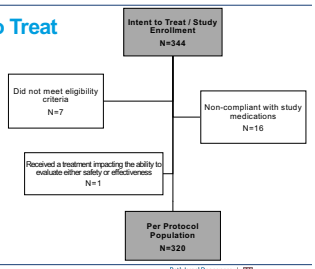
- 342/344 patients completed 30-day follow-up
- 1-year follow-up in progress

Study Compliance

Per Protocol vs Intent to Treat

Major Protocol Deviations include non-compliance with:
- DAPT / Statin medications
- Study eligibility criteria
- Treatment intervention impacting the ability to evaluate endpoints
- Obtaining informed consent

Overall MPD rate = 7.0%



Patient Demographics

Parameter	ITT (n=344)	PP (n=320)
Age (years)		
18-64	23.3% (80)	23.1% (74)
65-69	20.6% (71)	20.9% (67)
70-74	31.4% (108)	31.6% (101)
75-79	24.7% (85)	24.4% (78)
Gender		
Male	57.3% (197)	57.5% (184)
Female	42.7% (147)	42.5% (136)

Patient Clinical Characteristics

Parameter	ITT (n=344)	PP (n=320)
Symptomatic	16.3% (56)	15.3% (49)
Previous Stroke	17.4% (60)	16.6% (53)
Previous Ipsilateral TIA	9.0% (31)	9.4% (30)
Previous Ipsilateral Amaurosis Fugax	4.9% (17)	4.7% (15)
Diabetes	34.0% (117)	34.7% (111)
Hypertension	87.5% (301)	87.8% (281)
Hyperlipidemia	90.1% (310)	90.0% (288)
Smoking History		
Current	23.5% (81)	23.4% (75)
Prior	44.5% (153)	45.0% (144)
Previous MI	15.7% (54)	14.7% (47)
Previous CEA (contralateral)	11.6% (40)	12.2% (39)
Previous CAS (contralateral)	5.8% (20)	6.3% (20)
PAD	25.9% (89)	25.6% (82)

Symptomatic Patients	ITT (n=56)	PP (n=49)
TCAR within 2 weeks of previous neurologic event*	25.0% (14)	24.5% (12)

*Event = previous ipsilateral stroke, TIA, amaurosis fugax

Baseline Lesion Characteristics

Parameter	ITT (n=344)	PP (n=320)
Lesion Treated		
ICA	52.3% (180)	53.7% (172)
CCA + ICA	47.7% (164)	46.3% (148)
% Stenosis		
50-59%	0.6% (2)	0.6% (2)
60-69%	5.5% (19)	5.6% (18)
70-79%	41.9% (144)	41.9% (134)
80-89%	33.4% (115)	34.1% (109)
90-99%	18.6% (64)	17.8% (57)
Lesion Length (mm)	23.3	23.0
Lesion Calcification		
None	34.6% (119)	34.7% (111)
≤ 25% circumferential	29.7% (102)	30.0% (96)
26-50% circumferential	18.6% (64)	19.1% (61)
51-99% circumferential	16.6% (57)	15.6% (50)
100% circumferential	0.3% (1)	0.3% (1)
Protruding into lumen	0.3% (1)	0.3% (1)

Parameter	ITT (n=344)	PP (n=320)
Tortuosity of CCA		
Mild	54.4% (187)	54.1% (173)
Moderate	13.1% (45)	12.5% (40)
Severe	1.7% (6)	1.9% (6)
Arch Type		
Type I	49.7% (171)	49.1% (157)
Type II	36.9% (127)	37.2% (119)
Type III	10.5% (36)	10.6% (34)
Atheroma in Arch	29.1% (100)	28.1% (90)

TCAR Procedural Information

Parameter	ITT (n=344)	PP (n=320)
Anesthesia Type		
General	85.2% (293)	84.4% (271)
Local anesthesia	11.9% (41)	12.5% (40)
Regional block	2.9% (10)	2.8% (9)
Procedural time (min)	56.6	56.9
Reverse flow time (min)	9.0	9.0
Intolerance	0%	0%
Procedure completion	100%	100%

30-Day Outcomes

Independent Neurological Assessments CEC adjudicated results

Parameter	ITT (n=344)	PP (n=320)
Stroke	0.9% (3)	0.6% (2)
Death	None	
MI	None	
Stroke/Death/MI	0.9% (3)	0.6% (2)

Primary Endpoint of 30d S/D/MI & 1yr ipsilateral stroke: pending 1yr results

30-Day Outcomes – Stroke Type

Independent Neurological Assessments CEC adjudicated results

Type	ITT (n=344)	PP (n=320)	NIHSS at 30-days
Major Ischemic	0.3% (1)	0.3% (1)	6
Minor Ischemic	0.3% (1)	0.3% (1)	0
Major Hemorrhagic	0.3% (1)	0	2

ITT – Intention-to-treat
PP – Per protocol
NIHSS – National Institute of Health Stroke Scale

30-Day S/D/MI

By Symptomatic Status

Parameter	ITT Population Symptomatic (n=56)	ITT Population Asymptomatic (n=288)	Per Protocol Population Symptomatic (n=49)	Per Protocol Population Asymptomatic (n=271)
Stroke/Death/MI	0	1.0% (3)	0	0.7% (2)
Stroke	0	1.0% (3)	0	0.7% (2)

No Death or MI events

No significant difference based on symptomatic status; P <0.5

Other Events Through 30-Days

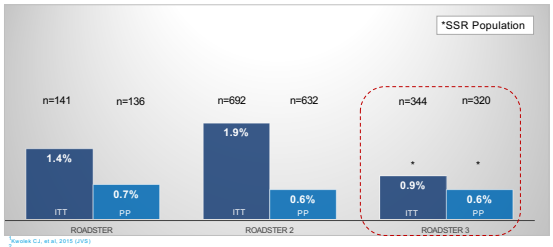
CNIs (CEC Adjudicated)

Parameter	ITT n=344	PP n=320	Status
CNI (voice hoarseness)	0.6% (2)	0.6% (2)	Both resolved within 6mo

Other Events (Site Reported Results)

Parameter	ITT n=344	PP n=320	
Access site complications	2.0% (7)	1.6% (5)	→ None resulted in stroke or CNI
Dissection	1.7% (6)	1.6% (5)	
Stent thrombosis / occlusion	0.3% (1)	0.3% (1)	→ Major ischemic stroke

ROADSTER: 30-Day Stroke Rates

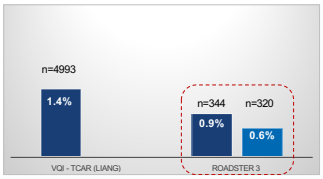


[1]Kaclek CJ, et al. 2015 (JVS)
[2]Kashyap VS, et al. 2020 (Stroke)

ROADSTER 3: 30-Day Stroke Rate

TCAR in SSR – VQI Data (2016-2020)

- Supported the label expansion for the ENROUTE Stent to include standard surgical risk patients



Liang et al, 2021 (JVS)

Conclusion

In the first-ever, independently adjudicated, prospective study evaluating TCAR in a SSR patient population:

TCAR is safe and effective in SSR patients with excellent clinical outcomes through 30-days

- **S/D/MI: 0.9% (0.6% PP)** → **Lower than in high-risk patients**
- **Stroke: 0.9% (0.6% PP)** → **Lowest stroke rate ever reported**

Forthcoming results:

- Pre-specified 1-year primary composite endpoint
- Long-term clinical outcomes through 5 years

Thank You

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