PROSPECTIVE, MULTICENTER EVALUATION OF TRANSCAROTID ARTERY REVASCULARIZATION (TCAR) IN STANDARD RISK PATIENTS: 30-DAY OUTCOMES OF THE ROADSTER 3 STUDY

Clinical Summary Sheet

Dermody, M. (2024). Prospective, Multicenter Evaluation of Transcarotid Artery Revascularization (TCAR) in Standard Risk Patients: 30-Day Outcomes of the ROADSTER 3 Study. Presented at VIVA Conference 2024.

Objective: First-ever prospective, multicenter, trial evaluating the safety and effectiveness of TCAR using the ENROUTE® Transcarotid Stent System (TSS) in conjunction with the ENROUTE® Transcarotid Neuroprotection System (NPS) for the treatment of carotid stenosis in **standard surgical risk patients**.

Methods: Between 2022-2024, 344 intent-to-treat (ITT) patients were enrolled (320 treated per-protocol (PP)) at 53 US sites. The primary endpoint for this single-arm, post-approval study is a composite of major adverse events (stroke, death, or myocardial infarction (MI)) through 30 days post-procedure, plus ipsilateral stroke from day 31 to 365 post-procedure. The incidence of cranial nerve injury (CNI) within 30 days post-procedure is a key secondary endpoint. All patients underwent independent neurological assessments before the procedure, within 24 hours, at 30-days, and at 1-year after TCAR. Events were adjudicated by an independent clinical events committee.

Findings: In the ITT population, 75.3% were less than 75 years of age, 42.7% were female, and 16.3% were symptomatic. Among symptomatic patients, 25.0% experienced a neurologic event within 2 weeks preceding the TCAR procedure. The mean lesion length was 23.3mm, 47.4% had a Type II or Type III aortic arch, and 17.2% of lesions had severe calcification.

In the ITT population, the **rate of stroke/death/MI at 30-days was 0.9% (0.6% PP) with a 30-day stroke rate of 0.9% (0.6% PP)**. There were no deaths or MIs through 30-day follow-up. The incidence of CNI within 30 days was 0.6% (0.6% PP); both resolved within 6 months.

Conclusions: These 30-day results of the ROADSTER 3 study demonstrate that TCAR, using the ENROUTE TSS in conjunction with the ENROUTE NPS, is safe and effective in patients at standard risk for adverse events from carotid endarterectomy.

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

CNI 0.6%

Resolved in 6 months

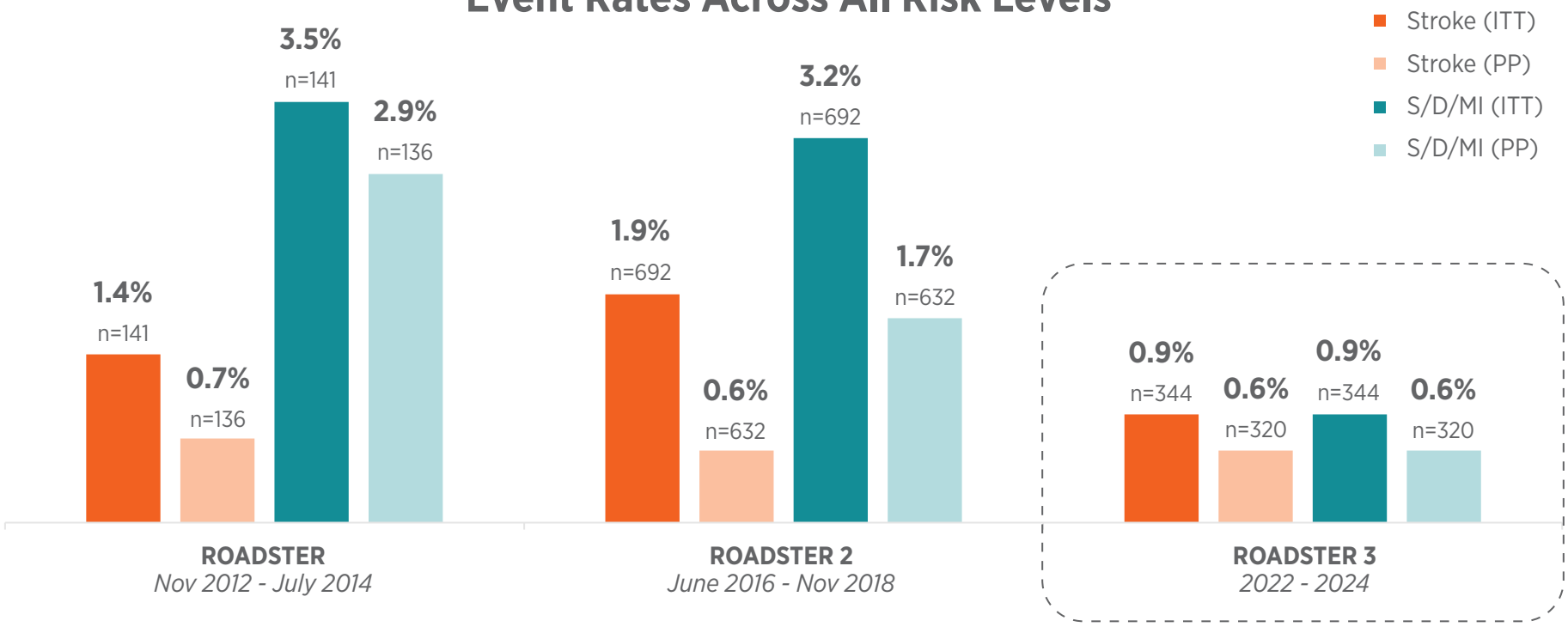
Lowest reported outcomes in SSR population.

Lower risk than in HSR patients.

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

No significant difference based on symptomatic status.

The ROADSTER Trials: Demonstrating Consistent, Low Adverse Event Rates Across All Risk Levels



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