



Society for Cardiovascular Angiography & Interventions Think Tank Proceedings

Carotid Artery Stenting



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Introduction

Each year at the Society for Cardiovascular Angiography & Interventions (SCAI) Annual Scientific Sessions meeting, collaborative Think Tanks involving interventional cardiologists, members of industry, and other subspecialty guest members are convened for each SCAI clinical practice area to discuss topics of particular interest to the group. This document presents the proceeding of the 2024 peripheral session, which focused on carotid artery stenting (CAS). The hope for this discussion was to identify needs and promote action by the participants, leading to a positive impact on patient care. This proceeding provides a summary of the discussion.

Despite the approval by the Food and Drug Administration of CAS for high surgical-risk patients with atherosclerotic carotid bifurcation disease in 2004, and the subsequent Food and Drug Administration approval of CAS in standard surgical-risk patients, the Centers for Medicare & Medicaid Services (CMS) had severely restricted coverage of CAS. Until recently, coverage was limited to patients with symptomatic carotid artery stenosis of $\geq 70\%$ deemed to be high risk for carotid endarterectomy (CEA) and those participating in approved investigational device exemption trials or post-market registries. Since the initial CMS decision in 2005, there have been multiple randomized data sets (including nearly 8000 subjects) that repeatedly demonstrate that the procedural safety and long-

term stroke prevention effectiveness of CAS are comparable with those of CEA for both symptomatic and asymptomatic patients at standard surgical risk.¹⁻⁴ In light of these data, the October 2023 CMS decision to expand national coverage determination for percutaneous transluminal angioplasty of the carotid artery concurrent with stenting⁵ was welcome news for many interventional cardiologists, vascular surgeons, neurosurgeons, and neurovascular interventionalists. Most importantly, future patients now have unrestricted access to all 3 carotid revascularization technologies: CEA, CAS, and transcarotid artery revascularization (TCAR).

Unfortunately, owing to the nearly 2-decade restrictions in CAS coverage, there has been a gradual but marked reduction in the number of experienced CAS operators, especially among the SCAI membership. Although many in the vascular surgery community have embraced TCAR and the neurointerventional community has developed a larger presence in CAS by virtue of their work in acute stroke therapies, it is incumbent that the larger interventional community develop an avenue for the expert CAS implanters to educate the less experienced as well as train new operators. This proceeding statement is a call to action to establish a formal curriculum to ensure uniform cognitive proficiency and technical training, with a goal of providing education for appropriate patient selection, patient counseling, procedural safety, quality metrics, and outcomes assessment. The members of the Think Tank propose a patient-centric training curriculum with involvement of

Abbreviations: CAS, carotid artery stenting; CEA, carotid endarterectomy; GDMT, guideline-directed medical therapy; SDM, shared decision-making; TCAR, transcarotid artery revascularization.

Keywords: carotid artery disease; carotid artery stenting; multidisciplinary; quality assurance; training curriculum; think tank.

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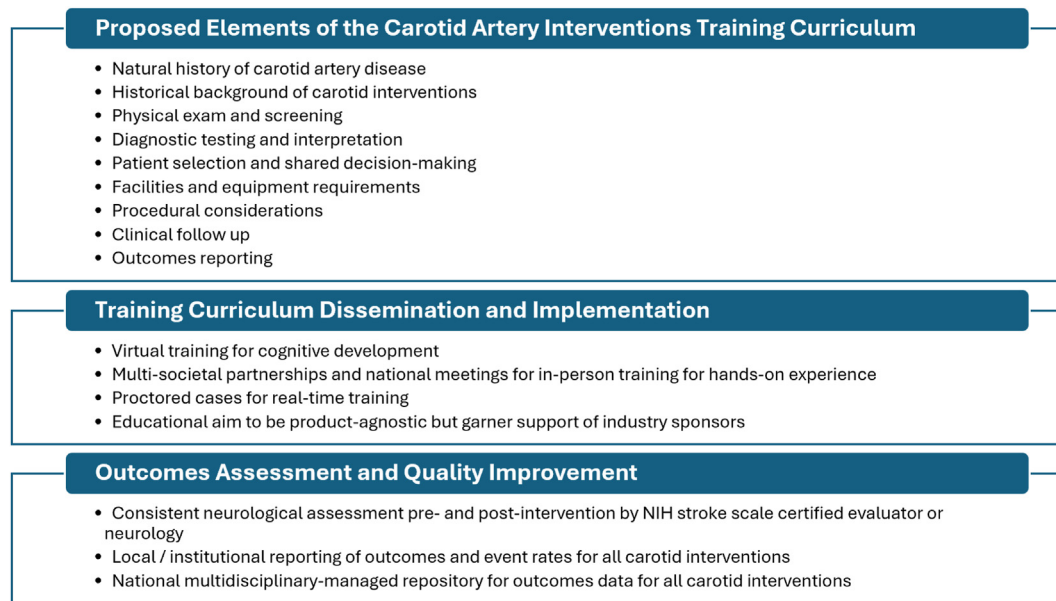


Figure 1.

A comprehensive overview of the 2024 SCAI Think Tank proceedings for carotid artery interventions, training, and quality improvement.

multiple subspecialties to fill this gap (Figure 1). It is hoped that this initial collaboration will formulate a basis of partnership across the disciplines to generate a multispecialty managed repository for outcomes reporting in carotid interventions.

Proposed elements of the carotid artery intervention training curriculum

Natural history of carotid artery disease

- Define the risk factors associated with carotid disease.
- Recognize the natural history of symptomatic and asymptomatic disease and its implications for scheduling follow-up imaging.
- Implement guideline-directed medical therapy (GDMT) to help mitigate the risks of disease progression and symptom development.
 - GDMT includes antiplatelet therapy as well as lipid, hypertension, and diabetes management.
 - Lifestyle modifications including smoking cessation, dietary adjustment, and exercise therapy are paramount to minimize overall cardiovascular risks.

Historical background of carotid interventions

- Recognize the context of trials as they relate to CAS, TCAR, and CEA, particularly given the extraordinarily rich historical background of carotid revascularization and the resultant large data sets generated by randomized controlled trials, single-arm prospective studies, postmarket registries, real-world evidence surveillance projects, and meta-analyses.

Physical examination and screening

- Identify patients at highest likelihood of carotid atherosclerosis and recognize deficiencies of physical examination.
- Differentiate patients who should undergo further screening with diagnostic imaging.

Diagnostic testing and interpretation

- Outline currently available imaging modalities, including duplex ultrasound, computed tomography angiography, magnetic

resonance angiography, and diagnostic digital subtraction angiography.

- Appraise appropriate use and timing of each imaging modality based on CMS guidance and patient-specific advantages and disadvantages, to ensure suitable testing is undertaken to allow informed decision-making.

Patient selection and shared decision-making

- Recognize that a large proportion of the patient population with carotid artery stenosis will fall within an area of clinical equipoise between the 3 interventional treatment strategies (CAS, CEA, and TCAR).
- Identify specific patient-related anatomical and/or clinical characteristics that may render some patients more appropriate for one therapeutic modality over others.
- Develop modules for shared decision-making (SDM) to guide discussions with patients regarding the types of revascularization procedures and potential risks vs benefits, considering individualized pre-existing comorbidities and patient preferences.
- Implement the SDM tool on every encounter with patients with carotid artery disease, regardless of treatment strategy.
- Document the performance of patient-centric SDM, to ensure compliance with CMS requirements.

Facilities and equipment requirements

- Maintain inventory of necessary tools for carotid angiography and intervention, including fluoroscopy equipment for digital subtraction angiography, catheters, wires, embolic protection devices, flow reversal devices, balloons, stents, bailout equipment, and closure devices.
- Prepare to manage adverse events that may occur during carotid stenting (eg, hemodynamic perturbations and flow reversal intolerance).
- Train support staff, including the nurses and radiation technologists, on the anticipated adverse outcomes with carotid interventions and how to treat them.

- Monitor meticulously for hemodynamic fluctuations to minimize cerebral hypoperfusion or risk of cerebral hemorrhage.
- Recognize changes in neurologic status and access site issues.
- Ensure readiness with medications, and so on.
- Administer hospital credentialing mechanisms for oversight of operators to ensure appropriate training certification is satisfied.
- Availability of preprocedural and post-procedural (CAS, TCAR, or CEA) neurologic assessment by neurology or National Institutes of Health stroke scale-certified evaluator, preferentially by an independent entity if feasible.

Procedural considerations

- Demonstrate detailed comprehension of the related angiography and optimal angles to allow visualization of treatment target and distal cerebral vasculature.
- Apply safe methods for carotid artery engagement and equipment passage.
- Review troubleshooting techniques for acute issues that arise during stent deployment process.
- Assure adequate training in the appropriate use of adjunctive medical therapy preprocedurally, periprocedurally, and postprocedurally.

Clinical follow-up

- Define an appropriate follow-up schedule and duplex imaging timetable.
- Provide GDMT to improve cardiovascular outcomes and duration of antiplatelet therapy.

Outcomes reporting

- Acknowledge expectations and standards for adverse outcomes.
- Administer quality oversight and outcomes reporting at the institutional level (mandatory) and potentially at the national level (optional).
- Report to a multidisciplinary-managed repository for outcome data and quality improvement, as this may assist in local quality assurance measures (optional).

Training curriculum dissemination and implementation

SCAI is open to collaboration with other professional societies to generate a comprehensive training curriculum, with instructors and trainees from across disciplines. Akin to other disease states,^{6,7} a concerted effort from multiple subspecialties in the interest of appropriate patient care delivery will optimize outcomes.

Given the recent decision from CMS, timing is of the utmost importance to ensure operators are well-trained and appropriately credentialed to deliver safe and effective options to patients. The proposed method of dissemination is to offer a hybrid approach of virtual and in-person training for the cognitive and technical aspects, respectively. Garnering the help of industry sponsorship, the envisioned pathway for a trainee is to (1) undergo cognitive development with virtual courses, (2) undergo in-person training for hands-on devices in a product-agnostic zone, and (3) treat proctored cases to provide real-time training. With a multisocietal partnership, the use of national meetings may help augment attendance for in-person training.

Future directions

It would be the intent of those involved with developing the training curriculum, and others, to codify in more detail the above-outlined necessary requirements and provide a reference for hospital credentialing and quality oversight bodies.

Peer review statement

Associate Editor Sahil A. Parikh had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Editor-in-Chief Alexandra J. Lansky.

Declaration of competing interests

Cody Bliss and David J. Minor are employed at W.L. Gore & Associates. Kevin Brounstein and Michael Kohler are employed at Shockwave Medical. Michael Kohler has equity interests in InspireMD and Shockwave Medical. Fely Canorea-Vega and Lindsay Farrel are employed at Abbott. Richard Dean and Chris Hughes are employed at Cordis. Gina Donnelly and Amy Newell are employed at and have equity interests in Corazon. Shane Gleason is employed at InspireMD. Joe McGonigle is employed at and has equity interests in Boston Scientific. Jorge O'Hara is employed at and has equity in Silk Road Medical Inc. Oscar Perez and Novena Rangwala are employed at GE Healthcare. Ravish Sachar is employed at Contego Medical. The other authors report no relevant financial interests.

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Ethics statement and patient consent

This manuscript does not report on patients or patient data; no ethical approval was sought or obtained.

References

1. White CJ, Brott TG, Gray WA, et al. Carotid artery stenting: JACC state-of-the-art review. *J Am Coll Cardiol*. 2022;80(2):155–170.
2. Rosenfield K, Matsumura JS, Chaturvedi S, et al. Randomized trial of stent versus surgery for asymptomatic carotid stenosis. *N Engl J Med*. 2016;374(11):1011–1020.
3. Halliday A, Bulbulia R, Bonati LH, et al. Second asymptomatic carotid surgery trial (ACST-2): a randomised comparison of carotid artery stenting versus carotid endarterectomy. *Lancet*. 2021;398(10305):1065–1073.
4. Reiff T, Eckstein HH, Mansmann U, et al. Carotid endarterectomy or stenting or best medical treatment alone for moderate-to-severe asymptomatic carotid artery stenosis: 5-year results of a multicentre, randomised controlled trial. *Lancet Neurol*. 2022;21(10):877–888.
5. Centers for Medicare & Medicaid Services. *Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting. Medicare Coverage Database*. Centers for Medicare & Medicaid Services; 2001.
6. Gornik HL, Aronow HD, Goodney PP, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2024;83(24):2497–2604.
7. Batchelor Wayne B, Anwaruddin S, Wang Dee D, et al. The multidisciplinary heart team in cardiovascular medicine: current role and future challenges. *JACC: Advances*. 2023;2(1):100160.