

Carotid Artery Stenting Versus Carotid Endarterectomy for Treatment of Asymptomatic Carotid Disease

R. Kevin Rogers, MD, MSc^a, Sanjay Gandhi, MD^b,
Kenneth Rosenfield, MD, MHCDS^{c,*}

KEYWORDS

• Asymptomatic carotid artery stenosis • Stroke • Carotid artery stent • Carotid endarterectomy

KEY POINTS

- Patients with asymptomatic carotid artery stenosis are at increased risk for stroke, which carries significant morbidity and mortality.
- Carotid artery revascularization with carotid endarterectomy has been shown in randomized trials that enrolled from 1983 to 2003 to reduce the risk for stroke in asymptomatic patients compared with medical therapy alone.
- There are limited level I data comparing carotid artery stent with carotid endarterectomy in asymptomatic patients with carotid artery stenosis.
- Based on current limited randomized and observational data, carotid artery stenting is noninferior to endarterectomy in clinical outcomes in patients at standard and high surgical risk with asymptomatic carotid artery stenosis.
- Operator volume and experience with patient selection play an important role in outcomes for carotid stenting; similarly, emerging techniques such as proximal embolic protection may also reduce adverse periprocedural events.
- Decision of revascularization strategy for a patient should be individualized based on the patient's clinical and anatomic lesion characteristics, the local operator experience, and patient preference.

INTRODUCTION

Revascularization of stenoses caused by atherosclerotic plaque that is not causing symptoms is generally not indicated for most vascular territories. However, disease of the carotid artery bifurcation is one of the few exceptions in which revascularization may be appropriate, even in the absence of

symptoms. Two decades ago, landmark trials comparing carotid endarterectomy (CEA) with medical therapy showed a clear benefit of stroke reduction in patients treated with surgery.¹⁻³ In 2000, carotid artery stenting (CAS) emerged as an available technical alternative to CEA for carotid revascularization. At present, 87% of carotid

Disclosures: R.K. Rogers is a site Principle Investigator for the SAPHIRE registry. S. Gandhi has no disclosures. K. Rosenfield is the National Co-PI for the ACT I study. He also receives compensation as member of Scientific Advisory Board for Abbott Vascular, the Medicines Company, and Vortex-Angiodynamics. He receives delayed royalty payments from Angioguard. His institution receives research funding from Cordis, Abbott Vascular, Bard-Lutonix, Silk Road, and Medtronic.

^a Section of Vascular Medicine and Intervention, Division of Cardiology, University of Colorado, 12401 E 17th Avenue, Aurora, CO 80045, USA; ^b Heart and Vascular Center, MetroHealth Campus, Case Western Reserve University, 2500 MetroHealth Drive, Cleveland, OH 44122, USA; ^c Section of Vascular Medicine and Intervention, Division of Cardiology, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114, USA

* Corresponding author.

E-mail address: krosenfield@fastmail.us

Intervent Cardiol Clin 3 (2014) 63–72

<http://dx.doi.org/10.1016/j.iccl.2013.09.009>

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revascularization procedures are performed for asymptomatic disease.⁴

Trials of CEA versus CAS have been the subject of much criticism and debate and, in particular, have highlighted the importance of case selection and operator experience for CAS. Most of these trials (CEA versus medical therapy and CEA versus CAS) have included patients who are of standard surgical risk, limiting the ability to generalize the evidence base to high-surgical-risk patients.^{1-3,5-8} The ability to generalize trials comparing CEA and CAS is further limited by pooling both symptomatic and asymptomatic patients, subgroups with clearly different event rates.⁵⁻⁹ This article summarizes the evidence base and related controversies regarding CEA versus CAS for the revascularization of carotid disease in asymptomatic patients.

INDICATIONS FOR REVASCUARIZATION OF ASYMPTOMATIC CAROTID STENOSIS

The indications for revascularization of asymptomatic carotid disease are based largely on the seminal trials of CEA versus medical therapy. These trials are summarized in **Table 1**. Each trial showed a substantial benefit of carotid endarterectomy compared with medical therapy for patients with greater than 60% to 70% asymptomatic carotid stenosis.¹⁻³ Several observations merit mention: (1) these trials enrolled primarily in the 1980s to 1990s and, as such, contemporary medical therapy was not available to many study participants. (2) Patients with medical comorbidities and/or anatomic high-risk features (eg, prior CEA or inaccessible lesion) were excluded. Additional selection biases may also have affected outcomes. (3) Life expectancy for participants was at least ~3 years, so that operative risks could be offset by longevity for overall benefit in stroke risk reduction. Although some argue that medical therapy has caught up to CEA, multisocietal guidelines indicate that CEA is appropriate for patients with low surgical risk and asymptomatic carotid stenoses greater than 70%.¹⁰

RANDOMIZED TRIAL EVIDENCE COMPARING CEA AND CAS IN STANDARD-SURGICAL-RISK PATIENTS

There are 4 large randomized trials comparing CAS with embolic protection with CEA in standard-surgical-risk patients and, of these,⁵⁻⁸ only 1 trial has included asymptomatic patients.⁸ In the Carotid Revascularization Endarterectomy versus Stenting (CREST) trial, standard-surgical-risk patients were randomized to CEA or CAS with distal embolic protection. Of 2502 randomized patients,

47% were asymptomatic. The primary outcome was not powered to enable comparison between therapies by symptomatic status. At 30 days, compared with the CEA group, there were trends for less myocardial infarction (MI) but more strokes in the CAS group; however, these differences were not statistically significant (**Table 2**). There were no deaths at 30 days for asymptomatic patients in either the CAS or CEA groups.

RANDOMIZED TRIAL EVIDENCE COMPARING CEA AND CAS IN HIGH-SURGICAL-RISK PATIENTS

Several clinical and anatomic features are generally accepted as conferring high-risk status to patients for CEA (**Box 1**). These variables have largely served as exclusion criteria in most carotid revascularization trials. Only 1 carotid revascularization trial has included solely high-surgical-risk patients.⁹

In the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial, 334 patients at high risk for CEA were randomized to CAS with distal embolic protection or CEA (**Table 3**). Approximately 70% of the study population was asymptomatic, but the trial was not powered to be analyzed by symptomatic status. The primary outcome was a composite of death, stroke, or MI within 30 days after revascularization and death or ipsilateral stroke between day 31 and 1 year. At 30 days, death, MI, and stroke occurred in 5.4% of asymptomatic patients having CAS and in 10.2% of the asymptomatic patients having CEA ($P = .20$). At 1 year in the asymptomatic subgroup, the primary outcome occurred in 9.9% of patients in the CAS arm and in 21.5% of patients in the CEA arm ($P = .02$ for comparison, $P = .55$ for test for interaction).⁹ At 3 years, strokes occurred in 10.3% of the asymptomatic patients having CAS and in 9.2% of asymptomatic participants with CEA.¹¹ Overall, based on this sample size and design, this finding should be interpreted as indicating that CAS is not inferior to CEA in asymptomatic patients at high risk for endarterectomy.

LIMITATIONS OF RANDOMIZED CONTROLLED TRIAL EVIDENCE COMPARING CEA WITH CAS IN ASYMPTOMATIC PATIENTS

A primary limitation of randomized trial evidence comparing CEA with CAS in asymptomatic patients is the paucity of level I data. Across the 4 trials of carotid stenting versus CEA in standard-surgical-risk patients, only 1175 of 5940 (20%) patients were asymptomatic.⁵⁻⁸ In the only trial of high-surgical-risk patients, 233 patients were asymptomatic.⁹

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