Long-Term Outcomes of Carotid Endarterectomy and Carotid Artery Stenting for Carotid Artery Stenosis: Real-World Status in Japan

Taichiro Imahori, MD, Kohkichi Hosoda, MD, PhD, Atsushi Fujita, MD, PhD, Yusuke Yamamoto, MD, Takashi Mizowaki, MD, PhD, Shigeru Miyake, MD, PhD, Hidehito Kimura, MD, PhD, Masaaki Kohta, MD, PhD, and Eiji Kohmura, MD, PhD

Background and Purpose: We investigated long-term outcomes of carotid endarterectomy (CEA) and carotid artery stenting (CAS) in our institute to evaluate the outcomes of real-world practice in Japan. *Methods:* Between August 2006 and July 2013, 203 consecutive carotid revascularizations with either CEA or CAS were performed in our institute. The initial treatment was regarded as the starting point in the cases of the patients who received treatment by bilateral carotid artery stenosis or retreatment. We assessed the long-term outcomes with survival analyses. *Results:* A total of 182 patients (CEA 111, CAS 71), including 86 symptomatic patients, were included in the current study with a mean follow-up period of 42.9 months. The periprocedural stroke/death/myocardial infarction (MI) rate was 3.6% for CEA and 5.6% for CAS groups ($P = .71$). Estimates of the 4-year event-free rate from the primary end point (the composite of any stroke, death, or MI within 30 days, and any ipsilateral stroke thereafter) using competing risk analysis were 3.6% for CEA and 7.1% for CAS ($P = .156$). Kaplan–Meier estimates of the 4-year event-free rate from the secondary end point (the composite of any stroke, death, or MI within 30 days, and any stroke or death thereafter) were 13.8% for CEA and 19.1% for CAS ($P = .072$). Age was the only significant predictor for the primary end point. Both age and CAS were significant predictors for the secondary end point. *Conclusions:* The current study on real-world practices demonstrated perioperative and long-term outcomes that were comparable to previous major studies of large numbers of patients. **Key Words:** Carotid artery stenosis—Carotid endarterectomy—Carotid artery stenting—Long-term outcomes.

Introduction

Carotid artery stenosis is one of the major causes of ischemic stroke. Carotid endarterectomy (CEA) has been demonstrated to be an excellent preventive treatment in reducing the occurrence of stroke for patients with moderate to severe symptomatic carotid stenosis and for those with severe asymptomatic stenosis.[1-4] As an alternative to CEA, carotid artery stenting (CAS), which has been considered to be less invasive than CEA, has become more frequently used for the treatment of carotid artery stenosis, especially in high-risk groups for CEA. The Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy study, which was aimed at high-risk groups, has shown that treatment with CAS is not inferior

From the Department of Neurosurgery, Kobe University Graduate School of Medicine, 7-5-1, Kusunoki-cho, Chuo-ku, Kobe 650-0017, Japan.

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Address correspondence to Kohkichi Hosoda, Department of Neurosurgery, Kobe University Graduate School of Medicine, 7-5-1, Kusunoki-cho, Chuo-ku, Kobe 650-0017, Japan. E-mail: khosoda@med.kobe-u.ac.jp.

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to CEA.[5] However, the peri-interventional stroke or death rates after CAS still exceed the rates found after CEA in recent randomized clinical trials (RCTs).[6-8] In addition, the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) showed that CEA was superior to CAS in patients older than or equal to 70 years of age.[9] On the other hand, some investigators have claimed that current medical intervention alone for vascular disease is preferable for preventing strokes associated with asymptomatic severe carotid artery stenosis.[10]

RCTs have many inclusion and exclusion criteria. Therefore, it is somewhat questionable whether the results of the RCTs performed in a selected group of patients can be extrapolated to daily practice. In the real world beyond RCTs, only a few reports of the long-term outcomes of CEA or CAS with survival analyses exist.[11-16]

The aim of the current study was to assess the long-term outcomes of CEA and CAS with a survival analysis in our institute outside an RCT.

Materials and Methods

Study Design

We performed a prospective cohort study using magnetic resonance plaque imaging in patients with cervical carotid artery stenosis to estimate the occurrence of new ischemic lesions following either a CEA or CAS.[17] Accordingly, we prospectively recruited patients who were being considered for either CEA or CAS beginning in August 2006. In the current study, we retrospectively reviewed the middle and long-term outcomes of these patients.

Between August 2006 and July 2013, 203 consecutive carotid revascularization procedures (120 CEAs and 83 CASs) for cervical carotid artery stenosis were performed in our institute. Revascularization treatment was indicated for the symptomatic patients with cervical carotid artery stenosis of 50% or higher, according to the measurement criteria of the North American Symptomatic Carotid Endarterectomy Trial.[1] Symptomatic patients were defined as those who had experienced an amaurosis fugax, transient ischemic attack, or stroke in the territory of the ipsilateral carotid artery within 6 months before entry. For asymptomatic patients, revascularization treatment with CEA was indicated for patients with stenosis of 60% or higher, according to the inclusion criteria of the Asymptomatic Carotid Atherosclerosis Study.[3] On the other hand, revascularization treatment with CAS was indicated for asymptomatic patients with stenosis of 80% or higher, according to the inclusion criteria of the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy.[5]

The surgeon or interventionist responsible for the patient determined the selection of either CEA or CAS. In general, CEA was considered as the first-line therapy for carotid artery stenosis with marked calcification and vascular kinking and tortuosity. CAS was indicated for patients with high bifurcations, for restenosis after CEA, and for those who preferred CAS to CEA. For the patients who appeared to be equally suitable for either CEA or CAS, the physician and the patient discussed the treatment policy and decided which method should be performed on a patient-by-patient basis.

Preoperative Studies

In all patients, ultrasonography, magnetic resonance imaging and angiography (MRI/A), including plaque imaging, computed tomographic angiography, and single-photon emission computed tomography were performed to evaluate the perioperative risks.

Cardiopulmonary screening was performed in all patients. Cardiologists and anesthesiologists were consulted about the patients' heart and pulmonary functions and to determine their amenability to general anesthesia on a patient-by-patient basis.

Surgical Procedures

Our surgical procedures for CEA and CAS have been previously reported.[14] In the cases of CEA, patients had been given at least 1 antiplatelet agent for a minimum of 7 days before the procedure. CEA was performed with the patient under general anesthesia, with somatosensory-evoked potential monitoring for the selective placement of a shunt. In the cases of CAS, patients had been given 2 antiplatelet agents for a minimum of 7 days before the procedure. The stenting procedures were performed with the patient under local anesthesia. An intravenous heparin bolus (5000 U) was given to elevate the activated clotting time to between 2- and 2.5-fold above the baseline values.

Outcome Measures

The primary end point was the composite of any stroke, death, or myocardial infarction (MI) within 30 days (perioperatively) and any ipsilateral stroke thereafter. The secondary end point was the composite of any stroke, death, or MI within 30 days (perioperatively), and any stroke or death thereafter.

Stroke was defined as an event with neurological symptoms lasting for 24 hours or more that were confirmed with imaging as ischemic or hemorrhagic lesions. MI was defined as an event with electrocardiographic evidence either with or without elevated cardiac enzymes (creatine kinase-myocardial band or troponin), which included angina pectoris. In the cases of the patients who received bilateral carotid artery stenosis treatment or retreatment for restenosis, the initial treatment was regarded as the starting point.