Carotid Angioplasty and Stenting vs Carotid Endarterectomy for Treatment of Asymptomatic Disease

Single-Center Experience

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Background: Carotid angioplasty and stenting (CAS) with embolic protection is an acceptable alternative to carotid endarterectomy (CEA) in selected patients with symptomatic cervical carotid artery disease. Whether outcomes after CAS are comparable to those after CEA in the larger population of patients with asymptomatic disease is unclear.

Hypothesis: Carotid angioplasty and stenting performed in patients with asymptomatic disease will result in early outcomes equivalent to those with CEA performed in patients with asymptomatic disease at our center and in 2 landmark studies of CEA.

Design: Single-center retrospective review.

Setting: Urban hospital.

Patients: Three hundred twenty-six patients (202 men [62%] and 124 women [38%]; mean age, 71 years) with asymptomatic carotid artery stenoses treated with either CAS (n=120) or CEA (n=206) between January 1, 2001, and December 31, 2006. Overall mean degree of stenosis was 81.2%.

Interventions: Carotid angioplasty and stenting was performed using self-expanding nitinol stents coupled with a mechanical embolic protection system. Carotid endarterectomy was performed using general anesthesia with selective shunting based on carotid stump pressure.

Main Outcome Measures: Stroke, myocardial infarction, and death rates at 30 days after surgery.

Results: At 30 days after surgery, there was no statistical difference between outcomes after CAS (2 strokes [1.7%], 2 myocardial infarctions [1.7%], and 1 death [0.8%]) compared with CEA (2 strokes [1.0%], 3 myocardial infarctions [1.5%], and no deaths).

Conclusion: Vascular surgeons who have advanced catheter-based skills can safely perform CAS in patients with asymptomatic disease with periprocedural results comparable to those with CEA.

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Approximately two-thirds of CEA procedures in the United States are performed in patients with asymptomatic disease. Risk reduction when CEA is performed because of asymptomatic disease is less than that for symptomatic disease. The Asymptomatic Carotid Atherosclerosis Study demonstrated a 5-year stroke rate of 5% compared with 11% for medical management, and more recently, the Asymptomatic Carotid Surgery Trial demonstrated a 5-year risk of stroke of 6.4% after CEA compared with 11% after medical management of asymptomatic stenosis of 60% or greater. Inasmuch as the 5-year risk of stroke with medical management is only approximately 2% per year,
any carotid intervention because of asymptomatic disease must have low perioperative morbidity and mortality to provide an adequate risk-benefit ratio for patients. In addition, patients must have a reasonable life expectancy to benefit from carotid intervention.

Carotid angioplasty and stenting (CAS) has been used as an alternative to CEA for stroke prevention. Although multiple trials comparing CAS with CEA and CAS registries including patients with asymptomatic disease have been published or are ongoing,7-15 the role of CAS in treating asymptomatic disease remains unclear. Medicare recently rejected a proposed expansion of coverage to include patients with asymptomatic stenosis of 80% or greater. Carotid angioplasty and stenting coverage for asymptomatic disease remains limited to clinical trials.

We report a single-center experience with CAS and CEA used to treat asymptomatic disease during the past 5 years in a mixed population of patients at high and standard risk. We hypothesized that our 30-day early outcomes for stroke, MI, and death would be equivalent with CAS and CEA.

METHODS

PATIENTS

All CAS and CEA procedures performed because of asymptomatic disease at Northwestern Memorial Hospital, Chicago, Illinois, between January 1, 2001, and December 31, 2006, were retrospectively reviewed using our institutional review board protocol. Patients who underwent another operation during the same hospital stay were excluded from the study. Patients underwent CAS or CEA because of carotid stenosis of 70% or greater demonstrated by 1 or more of the following examinations: angiography, duplex ultrasonography, magnetic resonance angiography, or computed tomographic angiography. Patients were evaluated for both CAS and CEA. Patients underwent CAS if they were at high surgical risk, desired CAS, or qualified for 1 of the ongoing CAS trials or registries at our center. High surgical risk was defined on the basis of anatomic criteria (surgically inaccessible lesion, ipsilateral neck irradiation, contralateral carotid occlusion, current tracheostomy, contralateral laryngeal nerve paralysis, previous ipsilateral carotid surgery, or previous ipsilateral radial neck surgery and irradiation) or clinical or physiologic criteria (age ≥80 years, end-stage liver disease, severe coronary or valvular heart disease, or severe pulmonary disease requiring home oxygen).

PROCEDURES

Carotid Angioplasty and Stenting

All procedures were performed by at least 1 of 3 endovascular surgeons (J.S.M., M.D.M., or M.K.E.) with a 0.014-wire small-vessel endovascular experience with 20 to 30 proctored CAS cases. All operations were performed using the femoral approach in an operating angiosuite with dedicated endovascular capabilities. Embolic protection devices (wire-base filter, distal balloon occlusion, or proximal balloon occlusion) were used in 117 of 120 procedures (97.5%). Self-expanding nitinol stents were used in all procedures. All patients received local anesthesia and monitored anesthesia care. Procedural details have been reported previously.16,17

Outcomes

Outcome measures were stroke, MI (troponin I level ≥0.5 ng/mL [to convert to micrograms per liter, multiply by 1.0]), and death. Secondary outcomes were length of stay after the procedure and other major and minor adverse events. The most serious complication per patient was recorded and used for analysis. Neurologic examinations were performed by the operating surgeon in the immediate postoperative period. If the patient was enrolled in an investigational trial, a neurologist evaluated the patient both preoperatively and postoperatively. Otherwise, a neurology consultation was obtained for any new noncranial nerve neurologic deficit in the immediate postoperative period. Any death or major or minor adverse event occurring within 30 days after either procedure was recorded. A “major stroke” was defined as a new neurologic deficit discovered in the postoperative period that persisted longer than 24 hours and/or increased the National Institutes of Health Stroke Scale score by 3 points. A “minor stroke” was defined as a deficit lasting longer than 24 hours without increasing the National Institutes of Health Stroke Scale by more than 3 points. A transient ischemic attack was defined as any neurologic deficit that resolved within 24 hours after onset. A “major adverse event” was defined as an event that required either endovascular or surgical reintervention between 24 and 48 hours after the index procedure, caused an unplanned increase in the level of care (not including intensive care unit monitoring owing to vasoactive medications because this was, in general, self-limited and lasted <12 hours), led to prolongation of hospital stay by more than 48 hours, or caused some permanent serious sequela. A “minor adverse event” was defined as an event that required no further therapy and, at most, caused an unplanned extension of hospital stay of less than 48 hours for observation. Hematomas were defined as substantial if they were at least 5 cm in diameter, prompted an additional study to rule out another vascular complication, or caused a delay in discharge for observation of the patient.

RESULTS

Patient Characteristics

Between January 1, 2001, and December 31, 2006, 326 of 607 carotid interventions were performed because of
asymptomatic disease. Asymptomatic disease was the indication in 121 of 189 CAS procedures (64.0%). Data for 1 patient in the CAS group were excluded because another operation was performed during the same hospital stay. Therefore, included in the analysis were 120 CAS procedures performed in 117 patients; 3 patients underwent sequential bilateral operations. Most CAS procedures (55.8%) were performed as part of a clinical trial or registry. Asymptomatic disease was the indication in 238 of 418 CEA procedures (56.9%). Data for 32 patients in the CEA group were excluded because another operation was performed during the same hospital stay. Therefore, the analysis was carried for 206 CEA procedures in 192 patients; 14 patients underwent other operation during the same hospital stay. Therefore, included in the analysis were 120 CAS procedures performed in 117 patients; 3 patients underwent sequential bilateral operations. Mean age in the CAS group was significantly higher compared with the CEA group: 72.4 (9.5) years (median age, 72.2 years; age range, 49-91 years) vs 70.4 (8.5) years (median age, 71.4 years; age range, 47-88 years; P = .047). In the 2 groups, sex (65.0 % vs 60.7% male; P = .43) and sidedness of the lesion (46.3% right vs 53.4% left; P = .19) were similar. Other baseline patient characteristics are given in Table 1. Patients undergoing CEA were more likely to be current smokers. More patients older than 80 years underwent CAS, and the American Society of Anesthesiologists classification overall was higher in patients in the CEA group. Otherwise, differences between baseline patient characteristics were not significant. High-risk criteria met in both groups are given in Table 2.

Carotid angioplasty and stenting was performed successfully in 120 of 124 patients, for a technical success rate of 96.8%. One patient had a bovine arch and an external carotid artery occlusion, and the operating surgeon was unable to advance the guiding sheath into the common carotid artery; 2 patients had preocclusive lesions that could not be crossed with a wire; and 1 patient had a preocclusive lesion that was crossed with a wire but could not be crossed with the filter device approved for the clinical trial in which she was a participant. All 4 CAS procedures with technical failures were converted to CEA. None of the 4 patients had an adverse outcome related to attempted CAS or a primary outcome event of stroke, MI, or death.

### THIRTY-DAY OUTCOME

The primary outcomes of stroke, MI, and death are given in Table 3. No significant differences were found between the 2 groups at 30-day follow-up. Two strokes occurred in the CAS group, both in patients who had distal embolic protection. One of these patients developed expressive aphasia and right-sided hemiparesis 30 minutes after the procedure was completed; a posterior middle cerebral artery distribution stroke was seen at diffusion-weighted magnetic resonance imaging. Symptoms had almost completely resolved by 30-day follow-up. In the other patient, right-sided homonymous hemianopsia was detected on the morning of postoperative day 1. At mag-
Nuclear resonance imaging, multiple infarcts were noted in the left posterior cerebral artery and left middle cerebral artery distributions and in the right cerebellar hemisphere. The patient was readmitted 17 days later because of hemorrhagic transformation of the left posterior cerebral artery distribution infarct.

Two strokes occurred in the CEA group. One of these patients was noted to have left upper and lower extremity weakness on emerging from general anesthesia. Repeated exploratory surgery was performed, with no occlusion or defect found at intraoperative angiography and no infarct seen at magnetic resonance imaging. There was full resolution of symptoms at 30-day follow-up. The other patient was noted to have slurred speech and left-sided facial drooping on postoperative day 1; however, a second exploratory surgery was not performed. Indeterminate age changes were seen at head computed tomography; magnetic resonance imaging was not performed because the patient had a pacemaker.

One death occurred in the CAS group (0.8%) as a result of an MI. This patient had severe bilateral carotid stenosis and 3-vessel coronary artery disease for which coronary artery bypass grafting had been offered but only if the patient underwent successful carotid intervention. This patient was home oxygen–dependent because of amiodarone–associated pulmonary fibrosis, had severe peripheral vascular disease with a right-sided toe ulcer due to diabetes mellitus, and had recently been admitted because of a non-ST elevation MI earlier in the month. The patient had a postoperative MI with cardiogenic shock and died 2 days after the CAS procedure. The other patient had a large postoperative MI and died 35 days after the CAS procedure after developing multiple organ system failure. The CAS was performed because of severe bilateral carotid disease, in preparation for coronary artery bypass grafting and aortic valve replacement surgery, that had been discovered after admission because of a non-ST elevation MI. Additional comorbidities in this patient included pulmonary fibrosis and chronic renal insufficiency (baseline creatinine concentration, 1.9 mg/dL [to convert to micromoles per liter, multiply by 88.4]). No deaths were observed in the CEA group.

Other adverse events are given in Table 4. As has been previously noted, substantially more patients were observed to have hypotension after CAS compared with CEA. There were 8 cranial nerve injuries (3.9%) in the CEA group: 4 marginal mandibular, 3 hypoglossal, and 1 recurrent laryngeal nerve palsy. Mean (SD) length of stay after the procedure was longer in the CAS group (1.85 [3.58]; median, 1 day) compared with the CEA group (1.26 [0.68]; median, 1 day).

Recent interest in CAS as an alternative to CEA for stroke prevention. There are several advantages to CAS in patients who have undergone previous neck operations or neck irradiation, which puts them at higher risk for cranial nerve injury during CEA. Carotid angioplasty and stenting is a percutaneous procedure performed with the patient under local anesthesia, which suggests that it should be better tolerated in patients at higher risk for cranial nerve injury during CEA.

Table 4. Postprocedure Morbidity

<table>
<thead>
<tr>
<th>Variable</th>
<th>CAS, No. (%) (n=120)</th>
<th>CEA, No. (%) (n=206)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major adverse events</td>
<td>13 (10.8)</td>
<td>16 (7.8)</td>
<td>.37</td>
</tr>
<tr>
<td>PSA requiring thrombin injection</td>
<td>1 (0.8)</td>
<td>3 (1.5)</td>
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<tr>
<td>Contrast agent–related nephropathy</td>
<td>2 (1.7)</td>
<td>1 (0.5)</td>
<td></td>
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<tr>
<td>Readmission</td>
<td>2 (1.7)</td>
<td>2 (1.0)</td>
<td></td>
</tr>
<tr>
<td>Delay in discharge because of hypertension or hypotension</td>
<td>2 (1.7)</td>
<td>2 (1.0)</td>
<td></td>
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<tr>
<td>SBO</td>
<td>1 (0.8)</td>
<td>1 (0.5)</td>
<td></td>
</tr>
<tr>
<td>Urinary retention</td>
<td>1 (0.8)</td>
<td>8 (3.9)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>17 (13.3)</td>
<td>7 (4.4)</td>
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<tr>
<td>Hypotension</td>
<td>1 (0.8)</td>
<td>5 (2.9)</td>
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<tr>
<td>Hematoma</td>
<td>3 (2.5)</td>
<td>3 (1.5)</td>
<td></td>
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<tr>
<td>Troponin leak</td>
<td>2 (1.7)</td>
<td>2 (1.0)</td>
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<tr>
<td>Transient ischemic attack</td>
<td>1 (0.8)</td>
<td>2 (1.0)</td>
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<tr>
<td>Retropertoneal bleeding</td>
<td>2 (1.7)</td>
<td>1 (0.5)</td>
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<tr>
<td>Visual defect</td>
<td>1 (0.8)</td>
<td>8 (3.9)</td>
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<tr>
<td>Headache</td>
<td>1 (0.8)</td>
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Abbreviations: CAS, carotid angioplasty and stenting; CCA, common carotid artery; CEA, carotid endarterectomy; DVT, deep venous thrombosis; ICU, intensive care unit; PSA, pseudoaneurysm; SBO, small-bowel obstruction.

Cross-references to relevant sections of the text.
in patients with symptomatic disease\textsuperscript{19,20} despite the use of embolic protection devices.

Carotid angioplasty and stenting for treatment of asymptomatic disease has been less well studied. High-risk patients and standard-risk patients with asymptomatic disease were included in 3 randomized trials that showed noninferiority of CAS to CEA.\textsuperscript{7,8,14} Two single-center reports, 1 randomized and the other a retrospective review, demonstrated equivalent results for CEA and CAS.\textsuperscript{9,21} Various industry-sponsored registry trials suggest that patients with asymptomatic disease undergoing CAS fare better than those with symptomatic disease.\textsuperscript{10,11,13} However, registry trials fail to include either a CEA or a medical management arm, relying on historical controls.

The CAS combined stroke and death rate of 2.5\% in our study compares favorably with the stroke and death rate for CEA from the same surgeons (1\%), the Asymptomatic Carotid Atherosclerosis Study (2.3\%), and the Asymptomatic Carotid Surgery Trial (2.8\%). Myocardial infarction was not reported for the Asymptomatic Carotid Atherosclerosis Study, but the Asymptomatic Carotid Surgery Trial combined stroke, MI, and death rate was 3.5\%. Although the combined stroke, MI, and death rate of 4.2\% in our CAS group was higher than the 2.4\% in the CEA group, the results were not statistically significant. This may be an effect of small sample size but more likely reflects the mixed cohort of high-risk and standard-risk patients in the CAS group. The major and minor adverse event rates were higher in patients older than 80 years in the CAS group compared with the CEA group (16.7\% and 26.7\% vs 6.9\% and 17.2\%, respectively), but these differences were not statistically significant owing to small sample size (31 patients in the CAS group and 28 patients in the CEA group).

Both major and minor adverse event rates were higher for CAS than for CEA, although the results did not reach statistical significance. This may reflect that patients in the CAS group had more comorbidities (as evidenced by their overall older age and higher American Society of Anesthesiologists classification). Especially of note were the 16.5\% of patients who developed hypertension (systolic pressure <90 mm Hg). Indeed, 10.8\% of patients in the CAS group were transferred to the intensive care unit overnight for observation, volume resuscitation, or pharmacologic support because of hypertension compared with 2.4\% of patients in the CEA group. The effects of this sustained hypertension and the measures used to treat it may account for the relatively high MI and death rates seen in high-risk trials for CAS despite the percutaneous nature of the procedure. These effects almost certainly had a role in the deaths in this series and probably also contributed to the MIs.

There are several limitations to this study. It was relatively small and the data were retrospectively analyzed. Patients were not randomized, and the patient groups were not strictly comparable. The results may not be applicable to other low-volume centers that do not routinely perform CAS because there is a relatively steep learning curve for this procedure.\textsuperscript{22} The low stroke, MI, and death rate from CEA observed in this series despite general anesthesia in all cases may be owing to the availability of specialized cardiovascular anesthesiologists and also may not be applicable to other centers. In addition, the availability of multiple high-risk carotid stent trials and registries may have caused direction of patients at high risk toward CAS and away from CEA, artificially improving the CEA results.

This series lends support to the hypothesis that CAS can be performed safely and with equivalent morbidity and mortality outcomes as with CEA in patients with asymptomatic disease. The surgical principle of careful patient selection must still apply, however, for centers to maintain acceptably low complication rates after carotid interventions to treat asymptomatic disease. Randomized controlled trials such as the Carotid Revascularization and Endarterectomy vs Stent Trial and the Asymptomatic Carotid Surgery Trial II are needed to definitively answer the question of whether CAS is comparable to CEA for treatment of asymptomatic carotid disease.

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Author Contributions: Dr Eskandari had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Tang, Morasch, and Eskandari. Acquisition of data: Tang, Matsumura, Morasch, Pearce, Nguyen, Amaranto, and Eskandari. Analysis and interpretation of data: Tang, Morasch, Amaranto, and Eskandari. Drafting of the manuscript: Tang, Nguyen, and Eskandari. Critical revision of the manuscript for important intellectual content: Tang, Matsumura, Morasch, Pearce, Amaranto, and Eskandari. Statistical analysis: Tang, Amaranto, and Eskandari. Administrative, technical, and material support: Tang, Matsumura, Morasch, Pearce, Nguyen, Amaranto, and Eskandari. Study supervision: Morasch and Eskandari.

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REFERENCES


DISCUSSION

M. Ashraf Mansour, MD, Grand Rapids, Michigan: This article reviews the outcomes of CAS and CEA in patients with asymptomatic disease. In this case-controlled study, approximately one-third of the patients underwent CAS and two-thirds underwent CEA. The overall combined stroke and death rate, 2.5% for CAS and 1% for CEA, is outstanding, reflecting the skill and expertise of the surgeons. I have 3 questions.

First, it is now routine and customary to use an embolic protection device in all carotid stent procedures; however, you note that in 6% of the cases an embolic protection device was not used. Were any of the strokes in the CAS group related to the use or lack of use of the embolic protection device? Second, in a previous report by Hobson et al,11 patients older than 80 years had worse outcomes with stenting. Based on your data, is CEA better than CAS in this age group? Third, as a surgeon performing both CAS and CEA, can you justify carotid stenting in a patient at good surgical risk with asymptomatic disease?

Dr Tang: In answer to the first question about embolic protection devices, 3 of the cases that did not have distal embolic protection were very early in our experience before it became clear that distal embolic protection decreased the stroke rate. In 2 patients, we were unable to pass the filter device and they did not receive embolic protection. None of the strokes were related to difficulty with embolic protection devices, and the 2 strokes occurred in patients who did have distal embolic protection.

In patients older than 80 years, we did not see any increase in either stroke or complication rate. However, these were small groups: only 30 patients in the CAS group and 28 patients in the CEA group. These numbers are too small to enable us to draw any conclusions. The literature suggests that in patients older than 80 years, the stroke rate is increased with CAS; therefore, until larger trials are completed, I think the best advice is to proceed with caution in these older patients.

In answer to your third question, I think our results suggest that even patients who are at good surgical risk have a low risk of stroke, MI, or death after CAS. From our experience, those patients could undergo CAS without difficulty.

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