Treatment of asymptomatic carotid artery disease: Similar early outcomes after carotid stenting for high-risk patients and endarterectomy for standard-risk patients

Leopoldo A. Marine, MD, Brian G. Rubin, MD, Rishindra Reddy, MD, Luis A. Sanchez, MD, Juan C. Parodi, MD, and **Gregorio A. Sicard,** *St. Louis, Mo*

Background: **The role of carotid angioplasty and stenting (CAS) in the treatment of asymptomatic patients with carotid disease remains controversial. The purpose of this report is to compare outcomes in asymptomatic patients treated with CAS and carotid endarterectomy (CEA). This was the initial experience performing CAS for most of the surgeons. For comparison, we also report our outcomes in standard-risk patients treated concurrently with CEA during the same period of time.**

Methods: **A retrospective, nonrandomized review of asymptomatic patients undergoing CEA or CAS at Washington University Medical Center in St. Louis was done. Patients with >70% asymptomatic carotid stenosis treated between September 2003 and April 2005 were identified. CEA was the first therapeutic consideration in all patients. CAS was reserved for high-risk patients. Thirty-day outcomes of stroke or death were recorded. During this time interval, 248 patients were treated including with 93 CAS and with 145 CEA. Symptomatic or clinically detected adverse outcomes such as myocardial infarction (MI), arrhythmia, renal failure, or pulmonary complications were noted but were not the primary end points of this review. This study addresses only the periprocedural outcomes of CEA and CAS in asymptomatic patients. No data >30-day follow-up are included.**

Results: **During this period, 93 CAS and 145 CEA procedures were done in asymptomatic patients. Patient characteristics in both groups were similar. Carotid protection devices were used in 91.4% of CAS patients. The results in the CAS group showed one death (1.1%) and one stroke (1.1%). In the CEA group, three strokes occurred (2.1%, $P = 0.9999$), one associated with death (0.7%, $P = 0.9999$). The CAS group had 1.34 ± 0.83 risk factors vs 0.39 ± 0.58 in the CEA group ($P < .0001$). Median CAS and CEA length of stay was 1 day.**

Conclusions: **CAS for asymptomatic carotid stenosis demonstrated equivalent outcomes compared with CEA, despite CAS being reserved for use in a disadvantaged subset of high-risk patients owing to anatomic risk factors or medical comorbidities. These results suggest CAS should be considered a reasonable treatment option in the high-risk but asymptomatic patient. Enthusiasm for CAS should be tempered by the recognition that long-term outcomes in CAS-treated asymptomatic patients remain unknown. (J Vasc Surg 2006;43:953-8.)**

The Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial recently reported the benefits of carotid angioplasty and stenting (CAS) in high-risk symptomatic patients.[1] This trial demonstrated that patients with high-risk anatomic or physiologic conditions treated with CAS achieved equal therapeutic efficacy with reduced rates of major morbidity or mortality compared with patients treated by carotid endarterectomy (CEA). The criteria used to identify the high-risk population within the SAPPHIRE Trial have provided care providers with a list of anatomic conditions and medical comorbidities that are believed to increase the risk of CEA. The United States Center for Medicare and Medicaid Services recently approved the reimbursement of this procedure limited only to the symptomatic patient subset.

In the United States however, most patients treated for carotid artery stenosis are asymptomatic. The outcomes of several important trials have established the advantages of CEA compared with medical treatment in asymptomatic patients with significant carotid stenosis.[2,3] In contrast, the multitude of completed or ongoing CAS trials and registries[4-11] have failed to resolve the role of CAS in the treatment of patients without symptoms. For these reasons, the role of CAS in asymptomatic patients with carotid disease remains unclear.

Our purpose is to report rates of the early adverse outcomes (0 to 30 days) of clinically apparent stroke or death resulting from CAS performed in consecutive asymptomatic patients. For comparison, similar outcomes of asymptomatic patients treated with CEA in a same time period are reported. The CEA was performed in standard-risk patients by experienced vascular surgeons with a high CEA volume. CAS was reserved for the subset of patients with high-risk anatomic or medical comorbidities, or both. One surgeon (J. C. P.) with prior CAS experience served as a proctor on all cases.

From the Department of Vascular Surgery, Washington University Medical Center.

Competition of interest: Dr. Parodi is a stockholder of the ArteriA device.

Correspondence: Leopoldo A. Marine, MD, Box 8109, 660 South Euclid Avenue St. Louis, MO 63110.

0741-5214/$32.00

doi:10.1016/j.jvs.2006.01.008

Table I. High-risk criteria for carotid stenting

	N = 93 (%)
Medical high risk*	56 (60.2)
Restenosis	26 (28.0)
High lesion†	15 (16.1)
Hostile neck‡	14 (15.1)
CN dysfunction§	3 (3.2)
ICA aneurysm	2 (2.2)
Fibromuscular dysplasia	1 (1.1)

CN, Cranial nerve; *ICA*, internal carotid artery.
*High-risk medical patients had one or more of the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial's criteria.
†Above level of C2.
‡Prior radical neck surgery, radiation therapy.
§Contralateral cord palsy.

METHODS

A retrospective, nonrandomized review of asymptomatic patients undergoing CEA or CAS at Washington University Medical Center in St. Louis was performed. Patients with >70% asymptomatic carotid stenosis treated between September 2003 and April 2005 were identified, and 30-day outcomes of clinically identified stroke or death were recorded. During this time interval, 248 patients were treated including with 93 CAS and with 145 CEA. Symptomatic or clinically detected adverse outcomes such as myocardial infarction, arrhythmia, renal failure, or pulmonary complications were noted but were not primary end points of this review. This study addresses only the periprocedural outcomes of CEA and CAS in asymptomatic patients; therefore, no data >30-day follow-up are included.

CAS patient data were prospectively collected in a CAS registry. CEA cases were retrospectively reviewed from all available hospital charts and clinical records. Data collection protocols were approved by the institutional review board. In all patients, CEA was the first therapeutic alternative considered. CAS was reserved for high-risk anatomic or medical conditions that potentially increased the risk of CEA (at least one of the conditions listed in Table I). It should be noted that the presence of medical comorbidities defined as high risk by the SAPPHIRE trial prompted consideration of—but did not mandate—CAS instead of CEA. Therefore, at the discretion of the surgeon, some patients deemed high risk by SAPPHIRE trial protocol still underwent CEA. Asymptomatic patients were required to have a documented carotid stenosis of ≥70% by preoperative imaging studies.

The risks and benefits of CAS and CEA were explained, and all patients gave informed consent. Patients with symptoms or with lesions of the origin of the common carotid artery, intracranial pathology, or undergoing combined cardiac and carotid procedures were excluded from the study. Patients whose asymptomatic carotid disease was managed medically were also excluded.

The degree of carotid artery stenosis was evaluated preoperatively with duplex ultrasound scanning. Other preoperative diagnostic studies that assessed cerebral circulation were used selectively and included computed tomography angiography (CAS, 15; CEA, 6), magnetic resonance angiography (CAS, 22; CEA,16), or neuroangiography (CAS, all cases; CEA, selectively in 18).

Patients received either 75 mg clopidogrel bisulfate daily beginning 72 hours before CAS or a loading dose of 300 mg immediately afterward, followed by 75 mg/day for at least 6 weeks. Patients undergoing CEA did not receive clopidogrel because of the potential increase in the risk of perioperative bleeding. Unless contraindicated, all patients stay on aspirin at a dose of 81 or 325 mg/day for life.

After the intervention, all patients went to an observation unit overnight or until hospital discharge for monitoring of arterial blood pressure and heart rate, a neurologic examination, and evaluation for adverse clinical events. Formal postoperative neurology consultation and brain-imaging evaluation were obtained only if there was any clinical suspicion of a neurologic event. Selective cardiac isoenzymes and electrocardiograms were not routinely checked and were only obtained in patients who had symptoms consistent with myocardial ischemia.

Patients were routinely discharged home from the observation unit on postoperative day 1. Each patient was subsequently scheduled for follow-up visits at 1, 3, 6, and 12 months after the intervention and annually thereafter. A color duplex ultrasonography scan was obtained on postoperative day 1 and at each follow-up visit.

Primary end points included death or any-cause stroke beginning with the procedure and including events ≤30 days afterwards, or both. *Stroke* was defined as a localized neurologic deficit that persisted >24 hours, with or without permanent deficit. Secondary end points included technical failure, myocardial infarction, or any other medical complication, cranial-nerve palsy, occlusion, or any other complication at the surgical site or the vascular access site. *Technical failure* was defined as inability to access, cross, or treat the lesion, or poststenting residual stenosis ≥30%. *Myocardial infarction* was defined as new pathologic changes on electrocardiogram associated with troponin elevation.

Statistical analyses. A statistician verified the descriptive statistics and conducted the statistical analyses using SAS (SAS Institute, Inc, Cary, NC). Continuous data were compared with the two-sample *t* test or the Wilcoxon two-sample test, whichever was appropriate. Categoric data were compared by using the χ^2 test or Fisher's exact test, whichever was appropriate. Differences were considered statistically significant if $P < .05$.

Procedural details. All CAS and CEA procedures were performed by the same team of vascular surgeons. Prior results of this group of surgeons met the 3% stroke plus death rate criteria of the American Heart Association (AHA). In contrast, other than the proctor for all CAS cases (J. C. P.), this was their initial experience performing CAS. Vascular surgery fellows participated in all cases and performed increasingly more complex portions of each case

commensurate with their endovascular experience and ability.

Carotid angioplasty and stenting. CAS cases were performed in an operating room using a mobile OEC 9800 C-arm fluoroscopic unit (General Electric Medical Systems, NY, NY). All procedures were done with the assistance of a proctor. The procedure was commonly performed with the patient under local anesthesia without sedation. Neurologic status was assessed at regular intervals by the anesthesiologist and surgeon. Intra-arterial blood pressure, heart rate, transcutaneous oxygen saturation, and electrocardiography were continuously monitored in all patients. There was no rigid protocol on the endovascular techniques used; this was individualized in a patient or case basis.

Percutaneous access was obtained through a common femoral artery puncture in 92 cases (98.9%) and a cut-down on the neck in one patient with severe tortuosity of the arteries. A diagnostic angiogram was done to evaluate the arch and great vessel origin anatomy. Selection of the common carotid artery was most commonly achieved by using a Vitek catheter on the left side (84.8% of the cases) or a JR4 catheter on the right side (78.7%) (Cook, Inc, Bloomington, Ind). Systemic, unfractionated intravenous heparin (100 U/kg) was given to obtain an activated clotting time of 250 to 300 seconds.

An angled-tip, stiff Terumo Glidewire (Boston Scientific Corp, Natick, MA) or an Amplatz ST-1 guidewire (Boston Scientific) was used to cannulate the common carotid artery and was then "buried" distally in the external carotid artery. A 100-cm-long 6F Shuttle sheath (Cook, Inc) was placed 2 to 4 cm proximal to the carotid bifurcation. Digital selective hand-injected angiography of the intracranial and extracranial arteries was performed in two different views.

After considering the characteristics of the lesion seen on selective angiography, the type of cerebral protection device was chosen. Cerebral protection devices were used in 85 cases (91.4%), most frequently the lesion was crossed with the 0.014-in-diameter, 300-cm-long EPI FilterWire EX (Boston Scientific Corp) (58.1%). In patients with tight or long stenosis, soft echogenic material related with the lesion, or highly tortuous carotid arteries, the ArteriA (ArteriA Medical Sciences, San Francisco, Calif) reversal of flow device was used (22.6%). Other protection devices included the Accunet filter (Guidant, Santa Clara, Calif) (10.8%). Combined protection devices were used in one patient. No protection device was used in eight cases due to severe tortuosity in five, carotid aneurysm in two, and re-restenosis after CEA in one.

Intravenous atropine sulfate (0.5-1.5 mg) was given routinely as a prophylactic measure before predilation, and the procedure was resumed only when a significant increase in the heart rate was seen. Predilatation was done with a low-profile monorail balloon in 71 cases (76.3%), most commonly an Ultra-soft SV Monorail balloon catheter (Boston Scientific) with a median size of 4 mm (range, 2.5 to 5.0 mm). Stent size was based on the diameter of the carotid artery. Most commonly, a self-expanding 8- × 21-mm monorail carotid stent Wallstent (Boston Scientific) (77.4%) was implanted. Other stents used included Acculink (Guidant) in 17.2%, Precise (Cordis Endovascular, Warren, NJ) in 3.2%, Bridge (Medtronic, Minneapolis, Minn) in 1.1%, or multiple stents in 7.5%. No stent was used in three patients: one with fibromuscular dysplasia, one with in-stent restenosis treated with a cutting-balloon, and one who was converted to open surgery. In 95.7% of the cases, the self-expanding stent was postdilated with a low-profile monorail balloon (most commonly Ultra-soft SV Monorail balloon catheter) with a median size of 5 mm (range, 4.0 to 6.0 mm).

Completion carotid angiography, including intracranial views, was performed in all patients to assess technical results, the presence of distal spasm, and to exclude distal cerebral embolization. At the end of the procedure, the protection device containing the captured emboli was removed and its content evaluated. The Shuttle sheath was removed over the guidewire in place and the groin puncture site was routinely closed with a Perclose femoral closure device (Abbott Labs, North Chicago, Ill).

Carotid endarterectomy. Surgeons most commonly performed CEA by using standard surgical techniques. This approach was used in 143 (98.6%) of 145 patients. A vein interposition graft was done in one patient, and a resection and end-to-end anastomosis was done in another, in both cases because of internal carotid artery tortuosity and kinking. The use of temporary shunting and patch closure was selectively done.

CEA was most commonly performed with local-regional anesthesia, without a shunt, and with patch angioplasty. A shunt was used in 67 cases (46.2%). A shunt was placed routinely in cases done with general anesthesia (97.7 %), but it was only done in 11.8% of the cases with local-regional anesthesia. Polyester patch angioplasty was used in 119 cases (82.1%), including in 87.5% of the female patients.

RESULTS

From September 2003 to April 2005, 349 carotid procedures were performed in 325 consecutive patients. CAS was done in 125 cases, 93 in asymptomatic patients (74.4%). CEA was performed in 224 cases, 145 in asymptomatic patients (64.7%). The characteristics of both the CEA and CAS asymptomatic groups are listed in Table II. The groups had similar baseline demographics (age and gender distribution). The mean age of the CAS group was 69.8 ± 10.2 years (median, 71; range, 47 to 91 years) and 63.4% were men. The group mean age for the CEA group was 69.6 ± 9.9 years (median, 69; range, 43 to 89 years) and 61.4% men.

A significantly greater incidence of comorbidities was seen in the CAS patient group, specifically for hypertension, coronary artery disease, congestive heart failure (CHF), chronic renal insufficiency, and chronic obstructive pulmonary disease (COPD) (Table II). When the incidence of risk factors was compared, the CAS group had a greater incidence of CHF, COPD, restenosis, hostile neck, and high

Table II. Patient comorbidities

	CAS *n = 145 (%)*	*CEA* *n = 93 (%)*	*P*
Diabetes mellitus	35 (37.6)	44 (30.3)	.2439
Dyslipidemia	70 (75.3)	97 (66.9)	.1684
Tobacco use	54 (58.1)	79 (54.5)	.5871
Age >80 years	17 (18.3)	29 (20.0)	.7429
Coronary artery disease	69 (74.2)	84 (57.9)	.0106
Myocardial infarction	31 (33.3)	38 (26.2)	.2371
Peripheral vascular disease	31 (33.3)	55 (37.9)	.4713
Congestive heart failure	24 (25.8)	12 (8.3)	.0002
Chronic renal insufficiency	21 (22.6)	9 (6.2)	.0002
End-stage renal disease	3 (3.2)	7 (4.8)	.7442
COPD	29 (31.2)	15 (10.3)	<.0001
Hypertension	85 (91.4)	112 (77.2)	.0048

CAS, Carotid angioplasty and stenting; *CEA,* carotid endarterectomy; *COPD,* chronic obstructive pulmonary disease.

Table III. Risk factors

Risk factors	*CAS* *n = 93 (%)*	*CEA* *n = 145 (%)*	*P*
Age >80 years	17 (18.3)	29 (20.0)	0.7429
CHF	24 (25.8)	12 (8.3)	0.0002
COPD	29 (31.2)	15 (10.3)	<.0001
Restenosis	26 (28.0)	0 (0)	<.0001
Hostile neck	14 (15.1)	0 (0)	<.0001
High lesion	15 (16.1)	0 (0)	<.0001
SAPPHIRE criteria	1.34 ± 0.83	0.39 ± 0.58	<.0001
Median	1	0	
Minimum	0	0	
Maximum	4	3	
Range	4	3	

CAS, Carotid angioplasty and stenting; *CEA,* carotid endarterectomy; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *SAPPHIRE,* Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy.

lesion (Table III). There was no significant difference in patients >80 years or in contralateral carotid occlusion between the two groups. These parameters were excluded in our definition of high-risk patients for CEA, as our past experience in treating both these populations has failed to demonstrate a significant increase in risk. However, retrospectively applying SAPPHIRE trial risk criteria revealed that the average number of SAPPHIRE parameters per patient was significantly more in the CAS group (1.34 ± 0.83 parameters) compared with the CEA group (0.39 ± 0.58 parameters, $P < .0001$).

The procedure was done by using local anesthesia without sedation in 90.2% of the total CAS cases. Four patients needed conversion to general anesthesia because of anxiety, seizures, stroke, and conversion to CEA, and six patients were done initially with general anesthesia. Anesthesia in the CEA group was driven by surgeon and patient preference and was most commonly done under local-regional anesthesia (63%), with general anesthesia used in 35.6% of the total cases. There was one conversion to general anesthesia because of patient anxiety.

The length of the procedure was trended towards being longer in the CEA group (123.5 ± 33.3 minutes; median, 115 minutes; range,90 to 210 minutes) compared with the CAS group (101.7 ± 39.1 minutes; median, 91 minutes; range, 42 to 270 minutes; $P = 0.0539$). It should be noted that the dataset for CEA operative times was incomplete, reflecting results for only 14 patients.

The estimated blood loss was greater in the CAS group (mean, 198.9 ± 124.8 mL; median, 200 mL; range, 50 to 700 mL) than in the CEA group (mean, 142.1 ± 98.2 mL; median, 100 mL; range, 20 to 800 mL; $P < .0001$), but there was no difference in the intraoperative intravenous fluids, with CAS at 1190.9 ± 531.7 mL (median, 1100 mL; range, 200 to 3000 mL) vs CEA at 1135.1 ± 565.4 mL (median, 1000 mL; range, 300 to 3000 mL; $P = .47$).

The median hospital stay was 1 day for both groups, with a difference in the mean length of stay for the two procedures of 3.2 ± 4.7 days for CAS (range, 0 to 29 days) vs 2.2 ± 3.7 days for CEA (range, 0 to 35 days) ($P = .0059$ by Wilcoxon test).

CAS was performed successfully in 92 of 93 patients (98.9% success rate). Completion angiography demonstrated residual stenosis in nine cases, all of them <30%. One CAS was converted to CEA. This patient had a dissection of the origin of the internal carotid artery with the tip of the Shuttle sheath and became symptomatic (transient ischemic attack). Conversion to surgery was done immediately, and the deficit had fully resolved within hours. This patient's data were analyzed in the CAS group based on an intention-to-treat basis.

Bradycardia was seen in nine CAS cases (9.7%) and intraoperative hypotension in 10 cases (10.8%). One patient had an intra-arterial injection of local anesthetic at the time of the completion angiography and had immediate seizures but recovered without sequelae. In another patient, a dissection flap in the common carotid artery developed at the proximal end of the stent. The patient was maintained on anticoagulation and has had no symptoms.

Five patients had complications related to the puncture site (5.4%): one retroperitoneal hematoma that was treated conservatively with transfusions and four groin hematomas, one of which required a femoral artery patch repair. No patient developed complications of the aorta or iliac arteries or cranial nerve palsy. In the 30-day follow-up, one patient with a challenging case of coiled ICA, which required two stents for correction, returned with occlusion of the stents and complained of dizziness, but had no focal deficit.

CEA was technically successful in all patients (100%). Cranial nerve palsy developed in four patients (2.8%) that persisted in the follow-up. Six patients had neck hematomas (4.1%), two of which required reintervention, the last with associated infection. Medical complications of CEA and CAS are presented in Table IV. The rate of postoperative medical complications between the two groups did not differ significantly. The most frequent medical complication was postprocedure arrhythmias, mainly bradycardia.

No significant differences were found in the primary outcome measures of stroke, death, or stroke plus death

Table IV. Postprocedure morbidity

Morbidity	*CAS n = 93 (%)*	*CEA n = 145 (%)*	*P*
Cardiac			
Arrhythmia	5 (5.4)	3 (2.1)	.2680
Ischemia	1 (1.1)	2 (1.4)	0.9999
Pulmonary			
COPD decompensation	1 (1.1)	1 (0.7)	0.9999
NC pulmonary edema	2 (2.2)	0 (0)	.1517
Pneumonia	1 (1.1)	1 (0.7)	0.9999
Renal failure	1 (1.1)	1 (0.7)	0.9999
Hematuria	3 (3.2)	1 (0.7)	.3023
Headache	1 (1.1)	1 (0.7)	0.9999
Hematoma	5 (5.4)	6 (4.1)	.7549
Seizures	1 (1.1)	0 (0)	.3908
Cranial nerve dysfunction	0 (0)	4 (2.8)	.1579

COPD, Chronic obstructive pulmonary disease; *NC,* noncardiogenic.

Table V. Major adverse events within 30 days

Adverse event	*CAS n = 93 (%)*	*CEA n = 145 (%)*	*P*
Stroke	1 (1.1)	3 (2.1)	0.9999
Hemispheric	1	2	
Occipital	0	1	
Death	1 (1.1)	1 (0.7)	0.9999
Stroke/death	2 (2.2)	3 (2.1)*	0.9999
MI	1 (1.1)	2 (1.4)	0.9999

MI, Myocardial infarction.
*One patient with both stroke and death.

(Table V) between the two groups at the 30-day follow-up. Only one stroke (1.1%) occurred in the CAS group. In the CEA group, there were three strokes (2.1%): one occurred contralateral to the side of the CEA, and one resulted in the patient's death. One death occurred within the 30-day period in the CAS group (1.1%). This was a high-risk medical patient who was treated with a right CAS for significant carotid stenosis before a planned staged cardiac procedure. The patient was discharged after CAS without complication. He died from respiratory failure after elective cardiac surgery done 10 days after CAS. In the CEA group, the only death (0.7%) occurred in the patient just described.

DISCUSSION

Several trials have shown CEA to be superior to medical management for the prevention of stroke in relatively healthy patients with moderate-to-severe asymptomatic carotid artery stenosis.[2,3] This difference is significant, although less striking than the benefits found in trials for CEA in symptomatic patients that were conducted by selected surgeons in high-volume surgical centers. High-risk asymptomatic patients (advanced age, medical comorbid conditions) were excluded from these trials. In clinical practice, however, asymptomatic high-risk patients routinely undergo carotid endarterectomy with substantially worse outcomes.[12-14] Ideally, CAS would allow us to benefit high-risk patients by treating their carotid lesions while sparing them the known risks associated with CEA.

The goal of this study was to compare the early outcomes of CAS in high-risk asymptomatic patients by using a concurrent standard-risk CEA group for comparison. The CEA group consisted of standard-risk patients who had outcomes comparable to results reported in the Asymptomatic Carotid Atherosclerosis Study (ACAS)[2] or Asymptomatic Carotid Surgery Trial.[3] Although still below the threshold level of acceptable results for CEA in asymptomatic patients according to AHA guidelines,[15] these results are substantially worse than our prior published experience, with an incidence of stroke of 1.2% in asymptomatic patients and a 30-day mortality of 1.0%.[16]

The CAS group had the disadvantages of being a new interventional technique for most members of the vascular surgical team, and it also was performed only in high-risk anatomic and medical patients. It must be acknowledge that an experienced CAS mentor (J. C. P.) was present for every case, although his input was typically limited to intraprocedural advice rather than technical assistance. These inherent biases might be predicted to result in a significant number of adverse outcomes for the CAS subgroup. Despite these shortcomings, no difference in early end points was identified between the CEA and CAS groups.

Potential explanations for the equivalent results in CAS-treated patients might include:

1. too small of a sample size to detect meaningful differences in outcomes between the two groups,
2. inadequate length of follow-up to detect a clinically important difference in outcomes in the intermediate and long term,
3. lack of screening for neurologic complications in both groups, or lack of independent neurologic evaluation before and after the procedures;
4. surgeons were able to triage the appropriate treatment for each patient and allocate their care to the appropriate group, or
5. the procedures are actually equivalently safe and efficacious.

The first two potential shortcomings are beyond the means of this report to address. Resolving these issues will require larger populations studied for longer periods of follow-up, potentially including patients already enrolled in large clinical trials or registries. The lack of routine neurologic examination by an independent examiner is clearly a shortcoming of this report but reflects the way carotid interventions are practiced in the real world.

CONCLUSION

Based on these results, we conclude that CAS in our high-risk subpopulation is equally as safe and effective as CEA is for standard-risk patients. These results suggest CAS should be considered a reasonable treatment option in the high-risk but asymptomatic patient. Enthusiasm for CAS should be tempered by the recognition that long-term

outcomes in CAS-treated asymptomatic patients remain unknown.

AUTHOR CONTRIBUTIONS

Conception and design: LM, BGR, RR, LAS, JCP, GAS
Analysis and interpretation: LM, BGR, RR, LAS, JCP, GAS
Data collection: LM, RR
Writing the article: LM, BGR, LAS
Critical revision of the article: LM, BGR, RR, LAS, JCP, GAS
Final approval of the article: LM, BGR, RR, LAS, JCP, GAS
Statistical analysis: LM, BGR, LAS
Obtained funding: GAS, JCP
Overall responsibility: BGR

We would like to thank David J. Dixon, PhD, Research Statistician in the Department of Biostatistics at the Washington University School of Medicine for his assistance in the performance and review of the statistics reported in this manuscript.

REFERENCES

1. Yadav JS, Wholey MH, Kuntz RE, Fayad P, Katzen BT, Mishkel GJ, et al. Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy Investigators. Protected carotid-artery stenting versus endarterectomy in high-risk patients. N Engl J Med 2004;351:1493-501.
2. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. JAMA 1995;273:1421-8.
3. Halliday A, Mansfield A, Marro J, Peto C, Peto R, Potter J, et al; MRC Asymptomatic Carotid Surgery Trial (ACST) Collaborative Group. Prevention of disabling and fatal strokes by successful carotid endarterectomy in patients without recent neurological symptoms: randomised controlled trial. Lancet 2004;363:1491-502.
4. Brown MM, Rogers J, Bland JM and the CAVATAS Investigators. Endovascular versus surgical treatment in patients with carotid stenosis in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): a randomized trial. Lancet 2001;357:1729-37.
5. Hobson RW II. Update on the Carotid Revascularization Endarterectomy vs. Stent Trial (CREST) protocol. J Am Coll Surg 2002;194(1 Suppl):S9-S14.
6. Zahn R, Roth E, Ischinger T, Mark B, Hochadel M, Zeymer U, et al. Carotid artery stenting in clinical practice results from the Carotid Artery Stenting (CAS)—registry of the Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte (ALKK). Z Kardiol 2005;94:163-72.
7. CARESS Steering Committee. Carotid Revascularization Using Endarterectomy or Stenting Systems (CaRESS) phase I clinical trial: 1-year results. J Vasc Surg 2005;42:213-9.
8. Alberts MJ, McCann R, Smith TP, Stack R, Roubin G, Schneck M, et al. A randomized trial of carotid stenting versus endarterectomy in patients with symptomatic carotid stenosis: study design. J Neurovasc Dis 1997; 2:228-34.
9. Featherstone RL, Brown MM, Coward LJ. International Carotid Stenting Study: Protocol for a randomised clinical trial comparing carotid stenting with endarterectomy in symptomatic carotid artery stenosis. Cerebrovasc Dis 2004;18:69-74.
10. Brooks WH, McClue RR, Jones MR, Coleman TC, Breathitt L. Carotid angioplasty and stenting versus carotid endarterectomy: randomized trial in a community hospital. J Am Coll Cardiol 2001;38:1589-95.
11. Ringleb P, Kunze A, Allengberg JR, Hennerici M, Jansen O, Maurer ?? et al. Evaluation of stent-protected angioplasty for therapy of symptomatic stenoses of the carotid artery. SPACE and other randomized trials. [German]. Nervenarzt 2003;74:482-8.
12. Ouriel K, Hertzer NR, Beven EG, O'hara PJ, Krajewski LP, Clair DG, et al. Preprocedural risk stratification: identifying an appropriate population for carotid stenting. J Vasc Surg 2001;33:728-32.
13. Wennberg DE, Lucas FL, Birkmeyer JD, Bredenberg CE, Fisher ES. Variation in carotid endarterectomy mortality in the Medicare population: trial hospitals, volume, and patient characteristics. JAMA 1998; 279:1278-81.
14. Chaturvedi S, Aggarwal R, Murugappan A. Results of carotid endarterectomy with prospective neurologist follow-up. Neurology 2000;55: 769-72.
15. Biller J, Feinberg WM, Castaldo JE, Whittemore AD, Harbaugh RE, Dempsey RJ, et al. Guidelines for carotid endarterectomy: a statement for healthcare professionals from a special writing group of the Stroke Council, American Heart Association. Stroke 1998;29:554-62.
16. Allen BT, Anderson CB, Rubin BG, Thompson RW, Flye MW, Young-Beyer P, et al. The influence of anesthetic technique on perioperative complications after carotid endarterectomy. J Vasc Surg 1994;19:834-42; discussion 842-3.

Submitted Aug 29, 2005; accepted Jan 14, 2006.