

A comparison of carotid angioplasty with stenting versus endarterectomy with regional anesthesia

William D. Jordan Jr, MD, David C. Voellinger, MD, Winfield S. Fisher, MD, David Redden, PhD, and Holt A. McDowell, MD, *Birmingham, Ala*

Introduction: Percutaneous transluminal angioplasty with stenting (PTAS) has been considered a potential alternative to carotid endarterectomy (CEA) for stroke prevention. Interventionalists have suggested that PTAS carries less anesthetic risk than CEA. The treatment of carotid stenosis with local or regional anesthesia (LRA) allows direct intraprocedural neurologic evaluation and avoids the potential risks of general anesthesia.

Methods: We retrospectively analyzed the clinical charts of 377 patients who underwent 414 procedures for the elective treatment of carotid stenosis in 433 cerebral hemispheres with LRA between August 1994 and May 1997. Group I (312 hemispheres) underwent PTAS, and group II (121 hemispheres) underwent CEA.

Results: The indications for treatment included the following: asymptomatic severe stenosis (n = 272; 62.8%), transient ischemic attack (TIA; n = 100; 23.1%), and prior stroke (n = 61; 14.1%). The early neurologic results for the patients in group I (n = 268) included 11 TIAs (4.1%), 23 strokes (8.6%), and 3 deaths (1.1%). The early neurologic results for the patients in group II (n = 109) included 2 TIAs (1.8%), one stroke (0.9%), and no deaths. The total stroke and death rates were 9.7% for the patients in group I and 0.9% for the patients in group II ($P = .0015$). The cardiopulmonary events that led to additional monitoring were evident after 96 procedures in group I (32.8%) and 21 procedures in group II (17.4%; $P = .002$).

Conclusion: PTAS carries a higher neurologic risk and requires more monitoring than CEA in the treatment of patients with carotid artery stenosis with LRA. The proposed benefit for the use of PTAS to avoid general anesthesia cannot be justified when compared with CEA performed with LRA. (*J Vasc Surg* 1998;28:397-403.)

Carotid endarterectomy (CEA) remains the standard of care for the treatment of high-grade stenosis of the extracranial carotid arteries.^{1,2} Recently, percutaneous transluminal angioplasty with stenting (PTAS) has been investigated as an alternative to CEA. As technologic advances have been made, the enthusiasm for this new procedure has increased.³⁻⁷ The rationale for the percutaneous approach to carotid occlusive disease includes reduced morbidity

rates, improved long-term patency rates, theoretically reduced costs, and less anesthetic risks. A higher rate of complications from angioplasty has been reported when compared with CEA.⁸ A review of the charges associated with these 2 procedures has shown that CEA remains a less costly procedure.⁹ This review evaluates the early clinical results of these 2 techniques for a subset of patients treated with local anesthesia.

METHODS

A review was performed for all patients who underwent elective treatment for carotid stenosis by means of either CEA or PTAS with local or regional anesthesia (LRA) between August 1994 and May 1997 at the University of Alabama at Birmingham Hospital and the Birmingham Veterans Administration Hospital. The clinic notes, hospital charts, and computerized registries were analyzed retrospectively for patient characteristics, indications for procedure, neurologic complications, and nonneurologic complications. The

From the Department of Surgery and Biostatistics, the University of Alabama at Birmingham.

Presented at the Twenty-second Annual Meeting of The Southern Association for Vascular Surgery, Rio Grande, Puerto Rico, Jan 21-24, 1998.

Reprint requests: William D. Jordan Jr, MD, The University of Alabama at Birmingham, 431 Kracke Bldg, 1922 7th Ave South, Birmingham, AL 35294.

Copyright © 1998 by The Society for Vascular Surgery and International Society for Cardiovascular Surgery, North American Chapter.

0741-5214/98/\$5.00 + 0 24/6/91218

Table I. Patient characteristics

	PTAS (n = 268)	CEA (n = 109)	P value
Male	184 (68.7%)	83 (76.1%)	.147
White	244 (91.0%)	102 (93.6%)	.476
Age	69 ± 10	68 ± 10	.568
Range	35 - 88	41 - 90	
CAD	165 (61.6%)	65 (59.6%)	.727
Hypertension	166 (61.9%)	63 (57.8%)	.358
Smoking	116 (43.3%)	67 (61.5%)	.001
Diabetes	61 (22.8%)	22 (20.2%)	.584
Procedures	293	121	
Cerebral hemispheres treated	312	121	

PTAS, Percutaneous transluminal angioplasty with stenting; CEA, carotid endarterectomy; CAD, coronary artery disease.

Table II. Indications for treatment

	PTAS (312 hemispheres)	CEA (121 hemispheres)
Asymptomatic	196 (62.8%)*	76 (62.8%)*
TIA	63 (20.2%)	37 (30.6%)
Prior CVA	53 (17.0%)	8 (6.6%)

PTAS, Percutaneous transluminal angioplasty with stenting; CEA, carotid endarterectomy; TIA, transient ischemic attack; CVA, cerebrovascular accident.

*P = 1, in comparison of symptomatic and asymptomatic groups.

patients who underwent treatment for acute strokes or who underwent percutaneous angioplasty without stenting (PTAS group only) were not included in this series. The patients were not randomized to treatment groups, and the treatment modality was decided on the basis of referral patterns and the choices of the treating physicians.

PTAS was accomplished with a coaxial femoral artery catheterization technique with local injection. After percutaneous femoral access was obtained, guiding catheters were positioned proximal to the bifurcation to image the stenosis before an appropriately sized balloon and stent wire were selected. Stenoses were crossed with a guidewire and predilated with a balloon. All patients in this series received at least 1 stent that was dilated with balloon inflation at pressures of 10 to 16 atm.

CEA was performed with local injection, regional cervical block, or both. Electroencephalogram monitoring and transcranial Doppler monitoring were commonly used. Primary closure, Dacron patch angioplasty, and internal carotid shortening were used as determined by the surgeon. Postoperative monitoring occurred in the postanesthesia care unit or in the intensive care unit (ICU), as governed by the treating team.

The patient characteristics reviewed were sex, age,

and pre-existing comorbidities, which included: coronary artery disease, hypertension, smoking, and diabetes. The indications for the procedure were divided into 3 groups: (1) asymptomatic, which included global, nonlateralizing symptoms of dizziness, syncope, or presyncope; (2) transient ischemic attack (TIA), which included amaurosis fugax; and (3) stroke. The neurologic event must have occurred within 3 months before the procedure to be considered a *symptomatic lesion*.¹⁰ TIAs had to be resolved within 24 hours, and strokes were classified as lasting longer than 24 hours. Neurologic complications were defined as either TIAs or strokes in the presence of lateralizing neurologic signs. *Minor strokes* caused minimal neurologic deficit that resolved with minimal or no deficit at the 30-day examination. *Major strokes* were defined as those deficits that lasted beyond 30 days and caused a change in the lifestyle of a patient.¹⁰

Additional cardiopulmonary monitoring was classified according to the need for intervention as related to physiologic changes after the procedure. Specifically, most patients were not placed in an ICU setting, but telemetry or frequent blood pressure monitoring were sometimes required to treat labile blood pressure or cardiac instability. Hypotension and bradycardia were counted as complications if the conditions were treated with additional intravenous fluids, inotropic agents, or atropine. Other events, such as neck or groin hematomas that necessitated operative evacuation or transfusion, were classified as requiring additional monitoring.

Statistical analyses were performed to compare patient characteristics, indications for intervention, and neurologic and nonneurologic results. The χ^2 test with Yates correction for continuity and the Fisher exact test, both 2-tailed, were used. The Fisher exact test was used when predicted continuity table cell values were less than 5. The Student *t* test was used to compare the ages of the patients in both

Table III. Neurologic results

	<i>PTAS</i> (268 patients)	<i>PTAS</i> (312 hemispheres)	<i>CEA</i> (109 patients)	<i>CEA</i> (121 hemispheres)
Asymptomatic	231 (86.2%)	270 (86.5%)	106 (97.2%)	118 (97.5%)
TIA	11 (4.1%)	15 (4.8%)	2 (1.8%)	2 (1.7%)
Minor stroke	19 (7.1%)	20 (6.4%)	1 (0.9%)	1 (0.8%)
Major stroke	4 (1.5%)	4 (1.3%)	0	0
Death	3 (1.1%)	3 (1.0%)	0	0
Total strokes and deaths	26 (9.7%)*	27 (8.7%)	1 (0.9%)*	1 (0.8%)

PTAS, Percutaneous transluminal angioplasty with stenting; *CEA*, carotid endarterectomy; *TIA*, transient ischemic attack.
**P* = .0015, in comparison of all strokes and deaths in the asymptomatic and TIA groups.

procedural groups. A *P* value of less than .05 was judged statistically significant.

RESULTS

We identified 377 patients who underwent 414 elective procedures for the treatment of 433 carotid stenoses with LRA either by *PTAS* or *CEA* between Aug 1994 and May 1997. Table I outlines the patient characteristics for each group, including a similarity between typical risk factors that are associated with patients who are treated for carotid stenosis.

Most patients underwent treatment of asymptomatic lesions that were identified from the presence of a bruit or from an investigation for nonlateralizing signs of cerebral ischemia (Table II). The proportion of patients who were symptomatic (37.2%) and asymptomatic (62.8%) was identical in each group.

The neurologic results between the 2 groups varied significantly, with a 9.7% total stroke and death rate for the patients in group I versus a 0.9% total stroke and death rate for the patients in group II (Table III). If the stroke rate is considered on the basis of the number of hemispheres treated, the total rate drops to 8.7% for group I and 0.8% for group II. The major stroke and death rate for group I was 2.6% (7 patients, 2 of whom were considered contralateral to side of treatment), and no major strokes or deaths occurred in group II. Twenty minor strokes were evident in the *PTAS* group—19 ipsilateral, 1 contralateral. All of these patients with minor strokes had minimal neurologic deficits that lasted more than 24 hours and were absent or minimal at the 30-day evaluation. Transient events were also more evident for the patients in group I (4.1%) as compared with the patients in group II (1.8%). All of these deficits resolved within 24 hours of the procedure. Two patients in the *PTAS* group had contralateral postprocedural strokes—1 minor, 1 major. These patients underwent additional *PTAS* to suc-

cessfully stabilize these new symptoms. These additional procedures were not counted in this series.

Ninety-six nonneurologic complications that necessitated additional cardiopulmonary monitoring were noted in 94 patients for *PTAS* (35.1%; Table IV). Most commonly, hypotension and bradycardia (87 patients) led to additional therapeutic intervention. Twenty-one similar complications were noted in 20 patients for *CEA* (18.3%; *P* = .002). Other nonneurologic complications were evident in 20 patients for *PTAS* and 3 patients for *CEA* (Table V) but did not lead to additional procedures or intensive monitoring.

DISCUSSION

Although *PTAS* is being investigated as a potential treatment for carotid stenosis, comparability must be established in several areas before acceptance as an alternative method. Any new therapy should undergo scrutiny to evaluate its efficacy in the light of its historical standard. Specifically, *CEA* has been established as the appropriate therapy in high-grade stenosis of extracranial carotid arteries. *PTAS* cannot currently be recommended as a less-costly lower-risk alternative to *CEA*. One argument for the treatment of carotid stenosis with the percutaneous approach includes the avoidance of the risk of general anesthesia. However, *CEA* has been reported as a safe and effective procedure without general anesthesia.¹¹⁻¹³ We compared the results of our surgical experience with *CEA* with LRA along with the results for patients for *PTAS*, which is also performed with local anesthesia.

As the population has aged, the demand for operations on patients with more significant medical comorbidities has increased, as has the desire to decrease morbidity rates and lengths of hospital stays. Therefore the resurgence of *CEAs* without general anesthesia has occurred. One can argue that

Table IV. Nonneurologic complications that required cardiopulmonary monitoring

	PTAS (293 procedures)	CEA (121 procedures)
Asymptomatic	196 (62.8%)*	76 (62.8%)*
Hypotension	68	5
Bradycardia	19 (1 permanent pacemaker)	1*
Hypertension	1*	3
Hematoma	1*	5
Congestive heart failure	0	3
GI bleeding	3	0
Anemia	1	2
Retroperitoneal hematoma	1	0
Myocardial infarction	1	0
Pulmonary edema	1	1
Atrial fibrillation	0	1
Total	96 (32.8%)†	21 (17.4%)†

PTAS, Percutaneous transluminal angioplasty with stenting; CEA, carotid endarterectomy; GI, gastrointestinal.

*Patients with more than 1 complication.

† $P = .002$ in comparison of all monitored complications with the absence of complications.

Table V. Minor complications that did not require cardiopulmonary monitoring

PTAS (293 procedures)	CEA (121 procedures)
Increased creatinine of >0.5 (6)	Cranial nerve injury (2)
Urinary tract infection (6)	Aspiration pneumonia (1)
Hematomas not requiring transfusion (6)	
Lower extremity ischemia (1)	
Acute renal failure (1)	

PTAS, Percutaneous transluminal angioplasty with stenting; CEA, carotid endarterectomy.

LRA may reduce additional complications, both neurologic and nonneurologic, from the procedure.¹² In consideration of LRA for CEA and PTAS, a lower stroke and death rate is seen in the CEA group. There is also a lower rate of systemic physiologic changes that require an increased intensity of monitoring (eg, vital signs or therapeutic methods). Paradoxically, the CEA with LRA, although physically more invasive, is actually "physiologically" less invasive than the PTAS with LRA.

Currently, PTAS is performed with a research-guided Institutional Review Board protocol and involves careful prospective neurologic monitoring. This study includes additional retrospective review of hospital charts and computerized database records to further substantiate those results. The CEA group is evaluated on a regular basis by the surgical team, and intensive evaluation is done only in the presence of neurologic changes. Although differences may appear on the basis of the methodology of evaluation in these

2 groups, the presence of a neurologic change is easily identified in either group. The primary question for those patients who suffer minor neurologic events is the duration of the event. Even transient ischemic events were more evident in the PTAS group as compared with this CEA group. This may suggest that there is a higher rate of any neurologic change after the PTAS procedure. However, most of these minor strokes had near complete recovery at the 30-day evaluation. This may suggest that the ischemic event that occurs at the time of the procedure is stabilized and further ischemia is substantially reduced after the procedure is complete. This initial phenomenon may be related to embolization during the PTAS. We have evaluated a smaller subset of patients and found a significantly higher microembolization rate during the PTAS procedure when evaluated with transcranial Doppler monitoring.¹⁴

The total stroke and death rates between these 2 groups vary by an absolute rate of 8.8%. The low stroke rate of patients in group II reflects the standard success of CEA.¹⁵ The major stroke and death rate of patients in group I offers a potential usefulness for PTAS in symptomatic lesions that are not surgically accessible or in patients *in extremis* from acute neurologic events. The carotid surgeon then must consider whether the CEA can be done at a lower morbidity rate than PTAS before entertaining an endovascular therapy for these patients.

All but one of the PTAS procedures at our institution have been done with local anesthesia. CEA is accomplished with local or general anesthesia at our institution. We have previously reported a total stroke and death rate of 3.6% for CEA at our institution.⁸

This report reflects a subgroup with a lower stroke and death rate (0.9%) that may be related to the anesthetic technique. This anesthetic choice is primarily related to the patient, surgeon, and referring doctor's preferences. Therefore a selection bias exists in this group because only those patients who are suitable for a neck operation in the awake state are chosen. Those patients with severe hearing disorders or with whom the surgical team is unable to communicate usually cannot tolerate a procedure in this fashion. There are also those patients who are to be at extreme high risk for a general anesthetic who are selected for CEA with regional anesthesia. Regardless, both the patient at high risk and the patient at normal risk can undergo CEA with LRA with an acceptably low complication rate. Similarly, there exists some selection bias in the PTAS group. Patients who require general anesthesia, who undergo angioplasty without stenting, and who undergo angioplasty for total occlusion are excluded. These patients may represent a higher risk group for postprocedure stroke (data not shown). This report, instead, focuses on a subgroup of patients who were treated for carotid stenosis with regional anesthesia.

Nonneurologic complications are also an important consideration in the treatment of patients with carotid disease. We previously have reported a higher rate of nonneurologic complications associated with the percutaneous procedure in comparison with CEA.⁸ PTAS can cause continued distension of the carotid bulb, which can lead to pronounced bradycardia and hypotension. This phenomenon has also been known to occur with patients for CEA but has had minimal long-term sequelae. Two patients for PTAS in this series were found to have severe bradycardic complications: 1 patient required a pacemaker, and another patient had delayed bradycardia and eventually died. The monitoring of these patients after carotid treatment includes electrocardiogram monitoring and blood pressure monitoring. Most of these patients routinely were monitored in a non-ICU setting after the procedure. Occasionally, additional monitoring was required and included ICU care, telemetry monitoring, increased frequency of checking the vital signs, or an interarterial catheter. We found a higher requirement for monitoring in those patients who underwent PTAS as compared with CEA, which further shows that this percutaneous approach is a "physiologically" more invasive procedure that requires more monitoring.

Other studies have shown that CEA with regional anesthesia is safe, effective, and less costly.^{12,13,16,17} In an evaluation of hospital charges,

PTAS is more costly than CEA.⁹ A percutaneous approach to carotid stenosis cannot be justified to avoid general anesthesia. This disease, instead, can be treated by both percutaneous and traditional surgical means with LRA. Furthermore, these data suggest that CEA with LRA carries a significantly lower neurologic risk in comparison with PTAS. The term *percutaneous* implies that a procedure may be less invasive as compared with open surgical techniques. At times, a "less invasive" approach may be fraught with a paradoxically higher complication rate than the traditional standard therapy and should not be embraced without extensive scrutiny.

CONCLUSION

PTAS carries a significantly higher neurologic risk than CEA in the treatment of patients with carotid stenosis with regional anesthesia. We do not advocate the widespread application of PTAS for a primary treatment of carotid bifurcation stenoses. Instead, we reserve PTAS for specific situations in which surgical treatment is not appropriate. Currently, we do not consider PTAS an acceptable alternative to CEA, and therefore, we do not support further clinical investigation in a randomized fashion to ascertain a similarity between these 2 groups. As techniques are further modified and morbidity and mortality rates are reduced, further clinical investigations may be warranted.

We acknowledge the contributions of Dr Gary Roubin and Dr Sri Iyer, formerly of the Division of Cardiovascular Disease, and of Dr Camilo Gomez, the Department of Neurology.

REFERENCES

1. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. *N Engl J Med* 1991;325:445-53.
2. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. *JAMA* 1995;273:1421-8.
3. Wiggli U, Gratzl O. Transluminal angioplasty of stenotic carotid arteries: case reports and protocol. *AJNR* 1983;4:793-5.
4. Vitek J. Percutaneous transluminal angioplasty of the external carotid artery. *AJNR* 1983;4:796-9.
5. Theron J, Courteoux P, Alachkar F, Bouvard G, Maiza D. New triple coaxial catheter system for carotid angioplasty with cerebral protection. *AJNR* 1990;11:869-74.
6. Diethrich EB. Stenting in the carotid arteries: initial experience in 110 patients. *J Endovasc Surg* 1996;3:42-62.
7. Yadav JS, Roubin GS, Iyer S, Vitek J, King P, Jordan WD, et al. Elective stenting of the extracranial carotid arteries. *Circulation* 1997;95:376-81.
8. Jordan WD, Schroeder PT, Fisher WS, McDowell HA. A

- comparison of angioplasty with stenting versus endarterectomy for the treatment of carotid artery stenosis. *Ann Vasc Surg* 1997;11:2-8.
9. Jordan WD, Roye GD, Fisher WS III, Reddon D, McDowell HA. A cost comparison of angioplasty and stenting versus endarterectomy for the treatment of carotid artery stenosis. *J Vasc Surg* 1998;27:16-24.
 10. Baker JD, Rutherford RB, Bernstein EF, Courbier R, Ernst CB, Kempczinski RF, et al. Suggested standards for reports dealing with cerebrovascular disease. *J Vasc Surg* 1988; 8:721-9.
 11. 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;19:834-43.
 12. Coyle KA, Smith RB III, Salam AA, Dodson TF, Chaikof EL, Lumsden AB. Carotid endarterectomy in patients with contralateral carotid occlusion: review of a 10-year experience. *Cardiovasc Surg* 1996;4:71-5.
 13. Hafner CD, Evans WE. Carotid endarterectomy with local anesthesia: results and advantages. *J Vasc Surg* 1988;7:232-9.
 14. Jordan WD, Voellinger DC, Doblar DD, Pluscheva NP, McDowell HA. The clinical results of microemboli detected by transcranial Doppler monitoring in patients undergoing carotid angioplasty vs. carotid endarterectomy [abstract]. International Society for Cardiovascular Surgery. 1997 Sept 22; London, England.
 15. Hertzner NR, O'Hara PJ, Mascha EJ, Krajewski LP, Sullivan TM, Beven EG. Early outcome assessment for 2228 consecutive carotid endarterectomy procedures: the Cleveland Clinic experience from 1989 to 1995. *J Vasc Surg* 1997; 26:1-10.
 16. Kraiss LW, Kilberg L, Critch S, Johansen KH. Short-stay carotid endarterectomy is safe and cost effective. *Am J Surg* 1995;169:512-5.
 17. Collier PE. Carotid endarterectomy: a safe cost-efficient approach. *J Vasc Surg* 1992;16:926-33.

Submitted Jan 27, 1998; accepted Apr 21, 1998.

DISCUSSION

Dr G. Patrick Clagett (Dallas, Tex). There has been an alarming increase in angioplasty and stenting for carotid artery disease throughout the world. This has occurred despite the proof of efficacy, safety, and durability of the procedure. Therefore I applaud Dr Will Jordan and his colleagues for trying to shed some light on the problem in showing that carotid endarterectomy with local anesthesia is a platinum standard and that angioplasty by comparison looks like tarnished brass.

Despite my sympathy and yours—he is preaching to the choir, after all—this report will not be convincing to neurologists, internists, and others who care for these patients. It is retrospective, nonrandomized, subject to selection and interpretation bias, and not in agreement with other data from the University of Alabama. Drs Roubin and Yadav are prominent in their absence from the lineup of authorship on Dr Jordan's paper. Both have recent reports in the cardiology literature that claim better results from angioplasty and stenting. Dr Roubin claims a 99% technical success rate in 152 patients with no deaths and 2 major strokes (1.3%), and Dr Yadav reports that in 107 patients who were considered at high risk for endarterectomy, the incidence rate of major strokes and deaths was 2.8%. In both reports, the incidence rates of minor transient strokes were 5% to 7%. So, now we have multiple reports from the same institution reporting different results. Are you and the cardiologists from the University of Alabama reporting the same patients, and why are the outcomes different? Are you including in your analysis patients on the steep slope of the learning curve for angioplasty and stenting that perhaps Roubin and Yadav omitted from their reports? Was independent neu-

rologic assessment carried out on your patients and on those undergoing angioplasty and stent placement? I am a little disturbed by the large proportion of patients who were asymptomatic in both groups, about two thirds of all patients. Clearly, stroke and death rates in these ranges in the angioplasty group outweigh any benefit in these patients who were asymptomatic. My question asks what was the stroke and death rate among the patients who were symptomatic with 70% or greater stenosis? This is the group that hopefully will be studied in a randomized trial comparing angioplasty and stenting with carotid endarterectomy.

To date, we are left with retrospective data that show that angioplasty and stenting are either good or bad depending on your point of view and what journals you have read. Even the same patients from the same institutions have either good or bad results depending on who you believe. I personally believe Dr Jordan because I know him to be honest, forthright, and responsible. Others, however, will believe Drs Roubin and Yadav and their disciples. How do we sort out this dilemma? It is a major problem that will only continue to grow, not only at the University of Alabama but throughout the country. This is beginning to sound reminiscent of the arguments that went back and forth between surgeons and neurologists in favor of aspirin or carotid endarterectomy. It took a single, randomized trial of 659 patients over 2 years to settle a decade of bickering between surgeons, neurologists, and others. It is truly amazing how quickly things are settled in the cold light of science. Do you think that the same is true with regards to angioplasty and stenting? Thank you.

Dr William D. Jordan. I think that Dr Clagett cut

right to the quick of the problem. Perhaps it is the fact that he is right—I do preach to the choir—but by the same token, I hope that the choir knows the data, before the choir confronts the heathen, and has an opportunity to discuss the data with him.

I will try to answer some of your questions here. Specifically, you mention the previous publications that have come forth from the University of Alabama. I am most familiar with the one that was published in 1997 in which 107 patients were reported. I participated in the review of that group. I think that if you read that paper carefully—and I would encourage everyone who is interested in this topic to read that paper because the number that is quoted is the major stroke and death rate—you will find that all strokes and deaths are reported at a per-patient rate of 9.3%. Because of that “per-artery” rate or per-size rate and because sometimes in the cardiology literature there is a tendency to report results on the basis of arteries rather than hemispheres or sides, you might say that the stroke rate can be reduced to about 7.8%. And you are also right. It depends upon how you look at a major stroke versus a minor stroke. We still consider that a stroke lasts longer than 24 hours. It is not a transient ischemic attack. But it is a stroke, whether it be minor or major.

I have not included “learning-curve” cases. The first 5 cases done at the University of Alabama in 1994 were done without stents. Patient 5 had an acute thrombosis that had to be reopened and then had subsequent cerebral infarction and died. This patient is not included in the series. And there have been selected cases that are done without stents since that time. Those cases are typically

not reported, and I think it is because the angioplasty without stent has suboptimal results.

You asked about the patients who were symptomatic, and we did not have a formal breakdown of those patients and their stroke rates. However, there was 1 stroke in the endarterectomy group, and that occurred in a patient who was symptomatic and who suffered a stroke after surgery. There were 28 strokes and deaths in the angioplasty group, and roughly half of those were in patients who were symptomatic. So, that will give you some idea of the patients who were symptomatic. They represent roughly one third or more of the treated group, but they do have a slightly higher stroke rate.

Finally, I think we have come to the issue of a randomized trial. I think that has become a point of controversy and discussion in our own institution, and the 3 carotid surgeons who are represented in this paper have been very close to the angioplasty and stenting series. On the basis of our review of the data, we do not want to randomize patients. I cannot ethically tell my patient that I do not know which form of therapy is better, which is partly because I have seen the results of angioplasty. I realize that there are enormous pressures, essentially a runaway train, in the community and in the national community to proceed with this trial. There is 1 trial that is industry-sponsored and ongoing right now. I do need to recall the words of Dr DeBakey when he was asked to participate in the NASCET trial. He essentially said “No, I know the results.” It perhaps took several years before he was cleared. I can only say that I would hope to stand on the shoulders of surgical giants and perhaps see what is on the horizon. I will wait and see what the national community discovers on this issue. Thank you.