
Can Clinical Evaluation and Noninvasive Testing Substitute for Arteriography in the Evaluation of Carotid Artery Disease?

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The objective of this study was to prospectively assess the value of combining clinical assessment and noninvasive testing in predicting the spectrum of carotid bifurcation pathology, as subsequently proven by arteriography, in order to determine the safety and accuracy of performing carotid endarterectomy without angiography. A panel of eight specialists representing vascular surgery, neurology, and neurosurgery were presented with the history, physical findings, and noninvasive test results (GEE-OPG and duplex scan) of 85 patients. They were asked to make an anatomic prediction of the status of each carotid artery (170 arteries) as to whether the bifurcation was normal, ulcerated, had a hemodynamically significant stenosis, or was occluded. The predictions were then prospectively evaluated and correlated with angiographic findings; 159 of 170 (93.5%) carotid arteries were accurately characterized; 73 of 80 (91%) symptomatic carotid arteries and 86 of 90 (95.5%) asymptomatic arteries were correctly characterized; 61 of 61 (100%) stenoses of hemodynamic significance, nine of 14 (64.3%) ulcerations without stenosis, and 18 of 18 (100%) of total occlusions were accurately identified by the panel. Twenty-nine patients have subsequently had 32 carotid endarterectomies without angiography, and the predicted lesion was confirmed at the time of exploration. The combination of clinical assessment and noninvasive testing, particularly duplex scanning, when performed in a laboratory with validated accuracy may with defined qualification be safely used as a substitute for contrast angiography.

ADVANCES IN TECHNOLOGY for noninvasive examination of the carotid bifurcation has led to increasing accuracy in evaluating the percentage compromise of the lumen by an atherosclerotic plaque as well as the assessment of plaque topography and consistency. Although there are many retrospective reports documenting the accuracy of noninvasive tests in sorting out the hemodynamically important from the

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unimportant lesion when compared to arteriography,¹⁻⁵ there have been no prospective studies that have assessed the accuracy of clinical evaluation of patients with carotid artery disease when noninvasive testing results are added to the data base of history and physical examination. The objective of this study was to prospectively evaluate the ability of a group of clinicians to accurately predict the status of each carotid bifurcation in a group of patients by providing them with a composite data base consisting of history, physical examination, and noninvasive assessment. The accuracy of their prospective prediction capability is then assessed in comparison to the actual angiographic results. Finally, results are presented for a select group of patients who had carotid endarterectomy without preoperative angiography.

Materials and Methods

A panel of eight clinicians consisting of five vascular surgeons, two neurologists, and one neurologic surgeon, was assembled. Each individual was asked to assess the individual data base of 85 consecutive patients and to make a prediction for the anatomic or pathologic status for each of 170 carotid bifurcations. The options included normal artery, ulcerated plaque without hemodynamic compromise, a hemodynamically significant stenosis, or total occlusion of the internal carotid artery. Each clinician was asked to make this choice following review of the patient's history, physical findings, and results of noninvasive testing with GEE-OPG and duplex scanning using a Diasonics scanner (DRF-400PV). A disinterested individual, blinded to the results of the panel's statements, reviewed the angiograms of 170 ca-

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TABLE 1. Comparison of OPG and Duplex Scan with Respect to Angiographic Findings

	OPG (%)	Duplex Scan Stenosis (%)	Duplex Scan Occlusion (%)
Sensitivity	42.4	98.4	100
Specificity	94.9	93.4	100
False-positive	12.5	9	0
False-negative	34	1	0
Overall Accuracy	70.8	95.4	100
Positive predictive value	87.5	90.9	100
Negative predictive value	66	98.8	100

rotid bifurcations in the 85 patients to establish their anatomic/pathologic status.

If six or more of the eight clinicians accurately predicted the anatomic/pathologic status of a given carotid bifurcation, as judged by comparison with the angiographic findings, then this was considered a correct clinical diagnosis. If less than six clinicians correctly identified the anatomic/pathologic status, it was judged incorrect in the final analysis.

The clinical data for each of the 85 patients included age, sex, the presence or absence of focal monocular or hemispheric symptoms, or nonfocal symptoms. The presence or absence of risk factors including tobacco use, hypertension, diabetes mellitus, hyperlipidemia, coronary artery disease, and peripheral vascular disease was noted. Physical findings included blood pressure, status of peripheral pulses, presence or absence of carotid bruit, and any abnormal findings on neurologic examination.

The noninvasive data included the actual ophthalmic artery pressures and ophthalmic to brachial pressure ratio as measured with the GEE-OPG and a description of the duplex scan results including the findings with B-mode ultrasound and spectral analysis.

Results

Angiographic assessment of 170 carotid bifurcations revealed 61 hemodynamically significant stenoses involving the internal carotid artery (50–99.9%) and 18 totally occluded internal carotid arteries; 14 carotid bifurcations were found to have definite angiographic evidence of ulceration associated with a low profile plaque; 77 carotid bifurcations were pathologically insignificant. Pathologic insignificance is defined as a minimal plaque without visible ulceration or a normal appearing artery by angiographic criteria.

Overall Accuracy

Eighty carotid bifurcations had associated focal neurologic symptoms and 90 carotid bifurcations were judged to be totally asymptomatic. Using the data base from the patient's history and physical examination

alone, the anatomic/pathologic diagnosis of the status of the carotid bifurcation was accurately assessed in 111 of 170 arteries (65.3%). However, when the information from noninvasive testing including the GEE-OPG and duplex scan data were added to the data base, correct assessment of the status of the carotid bifurcation by the panel was increased to 159 of 170 (93.5%).

Diagnostic Accuracy by Symptomatic Status

History, physical examination, and noninvasive data enabled the panel to accurately identify and characterize the status of the carotid bifurcation in 28 of 31 (90.3%) carotid bifurcations in patients with hemispheric TIAs, 23 of 23 (100%) arteries associated with amaurosis fugax, ten of 12 (83.3%) arteries associated with prior stroke, 12 of 14 (85.7%) arteries in patients with global ischemic symptoms, and 86 of 90 (95.5%) carotid bifurcations that were asymptomatic.

The overall accuracy in determining the status of carotid bifurcations that generated symptoms was 73 of 80 (91.3%). When the symptomatic carotid bifurcation was associated with a hemodynamically significant stenosis, as judged by noninvasive testing, the panel correctly identified 62 of 65 (95.4%), and when the symptomatic carotid bifurcation had a hemodynamically insignificant stenosis, the panel identified 11 of 15 (73.3%).

The overall accuracy of the panel in assessing the asymptomatic carotid bifurcation was 86 of 90 (95.5%). When the asymptomatic carotid bifurcation had an abnormal noninvasive test, 26 of 30 (86.7%) were correctly identified by the panel. When the asymptomatic carotid bifurcation had normal noninvasive testing, 60 of 60 (100%) were accurately characterized by the panel.

Accuracy by Anatomic/Pathologic Status

The panel correctly identified all 61 carotid arteries with angiographically proven, hemodynamically significant lesions (100%). There were 18 totally occluded internal carotid arteries proven by angiography, and all 18 were correctly predicted by the panel (100%). The panel identified 72 of 77 (93.5%) anatomically insignificant lesions of the carotid bifurcation. However, only nine of 14 (64.3%) ulcerated lesions in low profile plaques were correctly predicted by the panel.

The Accuracy of Noninvasive Studies

Although it was not the specific intent to validate the tests performed in the vascular laboratory in this study, the data are available and may be helpful in evaluating the results.

Table 1 compares OPG and duplex scan with respect to sensitivity, specificity, false-positive, false-negative, overall accuracy, positive predictive value, and negative predictive value in differentiating the hemodynamically significant from the hemodynamically insignificant le-

sion. Finally, the table identifies these parameters with respect to the duplex scan's ability to recognize a totally occluded internal carotid artery.

Carotid Endarterectomy Without Angiography

Because of the results of the prospective evaluation, we decided to undertake a limited trial of carotid endarterectomy without angiography in selected cases. In the 24-month interval from October 1985, to October 1987, 32 carotid endarterectomies were performed in 29 patients. During that same time interval, 230 carotid endarterectomies were performed at the UCLA Medical Center. Thus, the 32 operations without angiography represented 14% of the total experience.

The patients ranged in age from 48 to 85 years (mean: 63 years). Ten operations were performed for hemispheric transient ischemic attacks, 14 operations for asymptomatic high grade stenosis (>80%), four operations for amaurosis fugax, two operations for prior stroke with resolution, and two operations for acute stroke. Hemispheric transient ischemic events and amaurosis fugax constituted the indication for operation in 44% of the cases, asymptomatic, high grade stenosis (>80%) accounted for 44% of the operations, and cerebral infarction was the indication for surgery in 12%.

In reviewing the reasons for proceeding with operation without angiography, five specific indications were identified. These are as follows: (1) renal insufficiency in four patients; (2) surgeon's preference in 14 patients; (3) allergy to iodinated contrast material in three patients; (4) the need for emergency operation in four patients; and (5) the need for concurrent operation in another anatomic region in four patients.

At the time of operation the operative findings confirmed findings by duplex scanning with respect to high grade stenosis in all 32 cases. Following carotid endarterectomy, a completion angiogram was performed to assess the technical result of operation and to view the intracranial circulation. In no instance were any additional angiographic findings noted that would have altered the decision to perform carotid endarterectomy.

There were no deaths or postoperative strokes. Total hospital stay ranged from 3 to 6 days with an average stay of 4 days for the entire group.

Discussion

There is no question that the anatomic/pathologic definition of the extracranial and intracranial circulation, as provided by contrast angiography, would be desirable data to obtain in all patients with cerebrovascular disease, provided that the data could be obtained without significant risk or that the benefits of information outweigh the risks of obtaining the information. In spite of the fact that contrast angiography has become safer

through the years, it still carries a significant risk of neurologic morbidity and mortality rates, often rivaling the risk of surgery itself. Mortality rates of 0.5% and major neurologic complications from angiography of up to 2.6% are currently documented.⁶⁻¹⁰ In a recent prospective study of 1517 angiograms, the neurologic complication rate for patients who were referred for evaluation of cerebrovascular disease was 4.2%. The fixed stroke rate was 0.6% and the mortality rate was 0.06%.¹⁰ These complication rates are similar to those reported from carotid endarterectomy performed in centers of excellence. It is not surprising that these complications occur, particularly with selective catheter angiography in patients with carotid bifurcation disease. The "jet" effect of the contrast stream emerging from the catheter tip in proximity to a fragile atheromatous plaque can act like a water pick in fragmenting a lesion resulting in cerebral emboli. This mechanism and the potential thromboembolic complications from the catheter itself and contrast reaction make it even more surprising that complication rates from angiography are as low as they are.

Noninvasive testing, particularly the combination of real-time imaging together with spectral analysis (duplex scanning) has revolutionized the diagnostic approach to a carotid bifurcation disease.^{2,5,11-13} Although contrast angiography used to be considered the diagnostic gold standard, a recent report by Goodson et al.¹⁴ suggests that duplex scanning may be more accurate than angiography in defining lesions at the carotid bifurcation. Using the actual surgical specimen as the gold standard of comparison, the sensitivity of duplex scanning in assessing percentage stenosis was 99% compared with 91% for angiography. The accuracy of identifying intimal surface abnormality with duplex scan was 92% compared with 64% for angiography. Ulceration identified at operation was accurately anticipated 90% of the time with duplex scanning but only 54% of the time by contrast angiography. It is clear that duplex scanning can at least equal if not surpass angiography in defining percentage of stenosis and surface topography. Finally, there is one area that B-mode imaging can characterize that is unique to that modality. B-mode can identify the consistency of the plaque itself, hard *versus* soft, and the possibility of intraplaque hemorrhage.^{15,16} These features may be the most important prognostic indicators of the future behavior of a given carotid bifurcation lesion. What types of information can angiography provide that is unavailable by noninvasive measurement? Angiography will document anatomic variation, occlusive disease of the arch vessels, intracranial occlusive disease, intracranial aneurysm, and tumors. How frequent (important) are those abnormalities and how will they affect or alter clinical and treatment decisions? With the advent of CT and MRI scanning, the unrecognized finding of a brain tumor by angiography is no

longer relevant. Occlusive disease of the arch vessels accounts for 6% of arterial pathology and should be anticipated by careful physical assessment. Intracranial occlusive disease is rare and when present concomitant with carotid bifurcation disease in symptomatic patients will usually not alter the decision to proceed with carotid endarterectomy. Two recent reports studying patients with such tandem lesions have failed to impart any prognostic significance to the carotid siphon stenosis.^{17,18} A retrospective review by Ricotta et al.¹⁹ of 111 patients in whom both angiographic and noninvasive data were available concluded that angiography added nothing to the clinical and noninvasive examination in over two-thirds of their patients with transient ischemic attacks or asymptomatic stenoses. The exception they identified were patients undergoing evaluation for non-hemispheric symptoms.¹⁹

This prospective study has demonstrated that a panel of eight experienced clinicians provided with a good history, physical examination, and noninvasive data had an overall accuracy in characterizing 170 carotid bifurcations in 85 patients of 93.5%. The panel was 100% accurate in identifying hemodynamically significant stenoses and 100% accurate in recognizing the 18 internal carotid arteries that were totally occluded.

What are the risks of basing a surgical decision on clinical and duplex scan data? The major risk rests with the accuracy of the vascular laboratory. Duplex scanning is a highly complex, technician-dependent examination. Before any surgeon decides to operate on the basis of duplex scan information, the accuracy of the laboratory must be carefully and scientifically established.

The possibility of operation without angiography, using noninvasive data alone, was initially suggested by Von Reutern et al.²⁰ Blackshear and Connor presented their experience with four patients who were allergic to contrast media and had five carotid bifurcation operations using ultrasonic imaging.²¹ Crew et al. reporting a combined experience from two institutions, described 65 patients successfully undergoing operation without angiography.²² Additional reports have supported this practice,^{23,24} including our experience with 29 patients over a 24-month interval. Based upon the collective experience, a limited trial of this approach appears to be warranted, providing that the laboratory's credentials are well established, the clinical criteria are appropriate, a CT scan is performed, and noninvasive imaging, preferably by duplex scanning, demonstrates an appropriate lesion.

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