

The relative contributions of carotid duplex scanning, magnetic resonance angiography, and cerebral arteriography to clinical decisionmaking: A prospective study in patients with carotid occlusive disease

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Purpose: Recent reports suggest that 80% to 90% of patients can safely undergo carotid endarterectomy on the basis of duplex scanning alone without cerebral angiography. Other investigators have recommended that a complementary imaging study such as magnetic resonance angiography (MRA) also be obtained.

Methods: We prospectively evaluated 103 consecutive patients with carotid occlusive disease. Eighty percent of patients were symptomatic. All 103 patients underwent duplex scanning and arteriography. Additional noninvasive tests included computed tomography, magnetic resonance imaging, and MRA in 50%, 56%, and 48% of patients, respectively. At a multispecialty conference all studies except angiograms were reviewed, and a treatment decision was made by a panel of attending vascular surgeons, neurosurgeons, and neurologists. The cerebral angiograms then were reviewed and changes made to final treatment plans were noted.

Results: After review of noninvasive studies, 30 of 103 of patients (29%) were believed to require arteriography because of diagnostic uncertainty of carotid occlusion in three patients, suggestion of nonatherosclerotic disease in four, suggestion of proximal disease in two, suboptimal noninvasive studies in one, and uncertainty of therapy despite good-quality noninvasive studies in 20 patients primarily with borderline stenoses and unclear symptoms. In 10 of these 30 patients (33%) management decisions were changed on the basis of angiogram results. Of the remaining 73 patients (71%) in whom the panel felt comfortable proceeding with operative or medical therapy without angiography, only one patient (1.4%) would have had management altered by results of angiography. MRA results concurred with duplex findings in 92% of studies, but did not alter management in any patient.

Conclusions: In patients with good-quality duplex images, focal atherosclerotic bifurcation disease, and clear clinical presentation, treatment decisions can be made without arteriography. In 30% of patients angiography is useful in clarifying decisionmaking. MRA is unlikely to influence management decisions and is thus rarely indicated. (*J Vasc Surg* 1996;23:950-6.)

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The benefit of carotid endarterectomy for high-grade internal carotid artery stenoses has been shown for symptomatic patients in the North American Symptomatic Carotid Endarterectomy Trial (NASCET)¹ and the European Carotid Surgery Trial (ECST),² and for asymptomatic patients in the recently completed Asymptomatic Carotid Atherosclerosis Study (ACAS).³ Each of these trials used angiography as the definitive diagnostic test to determine the degree of carotid artery stenosis and to select patients for surgery.

Recent studies, however, have questioned the role of arteriography as the gold standard in the evaluation of carotid occlusive disease.⁴⁻⁷ Angiography may underestimate the degree of carotid stenosis, particularly web-like lesions, and gives no hemodynamic or physiologic information. Contrast angiography has also been noted to have a 0.5% to 4% incidence of neurologic complications—almost half of the neurologic morbidity observed in ACAS was the direct result of angiography.³ Angiography also results in complications at the arterial puncture site in approximately 5% of patients and contrast-induced renal dysfunction in 1% to 5%. Obviously it would be beneficial and cost-effective if significant numbers of patients could be safely evaluated and treated for cerebrovascular disease without angiography.

Color-flow duplex imaging (CFD), and magnetic resonance angiography (MRA) are two noninvasive imaging methods that can detect and grade carotid bifurcation disease. Most centers routinely perform CFD as part of the initial workup of patients with cerebrovascular disease. CFD has been shown to correlate well with angiography.⁶⁻⁸ MRA renders an image similar to that of conventional arteriography, although it tends to overestimate the degree of stenosis.^{8,9} MRA has the advantage of imaging the intracranial circulation and, if combined with magnetic resonance imaging (MRI), can give accurate images of the brain parenchyma.¹⁰

Several centers have reported exemplary results of carotid endarterectomy performed with CFD alone or in combination with MRA.¹¹⁻¹⁵ Nonetheless, well-defined criteria to delineate patients who are amenable to noninvasive workup are not available. It has also proved difficult to develop criteria that reliably correlate CFD and MRA findings with arteriography,¹⁶⁻²¹ particularly to define the 70% angiographic stenosis that was found to be important in NASCET and ECST (which is even more difficult because NASCET and ECST used different criteria to define 70% angiographic stenosis).²²⁻²⁴

This study was undertaken to define the relative contribution of CFD, MRA, and angiography in a prospective protocol and to determine which patients could be safely managed on the basis of the findings of noninvasive studies. We also wished to delineate the need for MRA in the workup, particularly to see whether some patients could be spared arteriography on the basis of the result of MRA.

PATIENTS AND METHODS

Between July 1, 1994, and March 31, 1995, 110 consecutive patients were evaluated for cerebrovascu-

lar disease at the University Medical Center (and Tucson Veterans Administration [VA] Medical Center) and the University of Colorado (and Denver VA Medical Center). Seven patients eventually were excluded from the review as a result of protocol violations (explained below) leaving 103 patients for evaluation. Sixty-one patients were evaluated at the University of Arizona, 22 at the Denver VA, and 20 at the Tucson VA. Sixty-seven were male and 36 were female; the mean age was 68 years (range, 34 to 93 years).

Atherosclerotic risk factors were prevalent. Hypertension was present in 74% of patients, coronary artery disease in 54%, hyperlipidemia in 53%, and diabetes in 17%. Thirty-seven percent of patients were currently smoking, 51% had smoked in the past, and 12% had never smoked. Cerebrovascular symptoms were present in 80% of patients (transient ischemic attack in 34, recent stroke in 20, amaurosis fugax in 13, both transient ischemic attack and previous stroke in 12, and vertebrobasilar symptoms in 3). The remaining 20% were asymptomatic. Eighteen patients (17.5%) had undergone previous carotid endarterectomy (contralateral to current symptoms in 12, ipsilateral to current symptoms in 5, and bilateral in 1). At the time of presentation 62 patients (60%) were taking aspirin, nine patients (9%) warfarin, one patient (1%) ticlopidine, and one patient (1%) both aspirin and warfarin. Thirty patients (29%) were not receiving antiplatelet therapy or anticoagulants at the time of presentation.

For entry into the protocol all patients required CFD and angiography performed within 30 days of one another. Of the seven patients excluded from this review, five lacked angiography and two lacked CFD. All vascular laboratories that performed studies were accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories. We attempted to perform MRI and MRA in as many patients as possible. CFD images were obtained with an ATL Ultramark 9 HDI system (Advanced Technologies Laboratories; Bothell, Wash.) or an Ultrasonics 750 SD duplex imager (Ultrasonics Inc.; Yonkers, N.Y.). MRI and MRA were performed in a 1.5 Tesla Signa system (General Electric Corporation; Milwaukee, Wisc.). Angiograms were obtained with conventional and digital techniques on imaging systems manufactured by Toshiba (Tokyo, Japan) or Siemens (Erlangen, Germany).

CFD images were interpreted using criteria based on peak systolic and end diastolic frequencies in the internal carotid artery, along with internal carotid-to-common carotid artery ratios as sug-

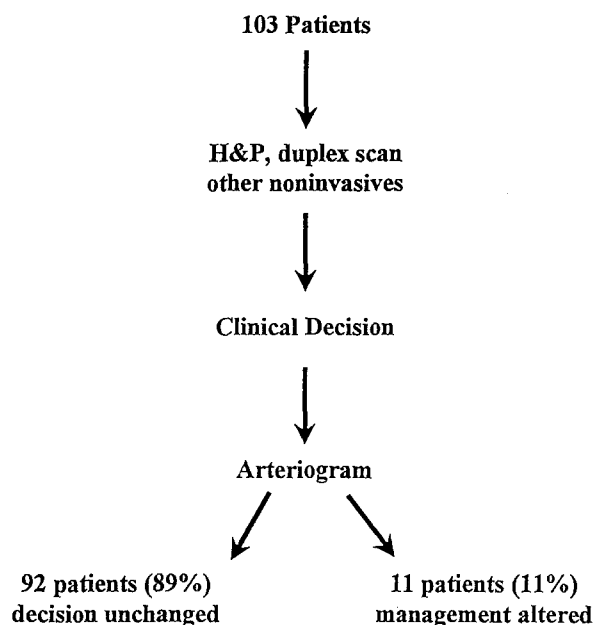


Fig. 1. Treatment decisions based on duplex scan alone were altered 11% of the time after arteriography.

gested by Moneta and associates²⁵ to better stratify patients within the 50% to 79% category of stenosis. Angiograms were interpreted using the measurement criteria set forth in NASCET (minimum ICA diameter compared with the normal ICA diameter distal to the stenosis).¹ MRA was performed both in 2D phase contrast with sagittal and coronal sections and in 2D time-of-flight with 1.5-mm transverse cuts. Phase contrast was used for a screening view and for the vertebrobasilar and intracranial arteries, whereas the time-of-flight sequences were used for maximal resolution of the carotid bifurcation. Available computer software did not provide interpretable images of the aortic arch or supraaortic trunks. Computed tomographic (CT) images of the brain were included if available (all performed on new-generation scanner).

All cases were presented at a multidisciplinary cerebrovascular conference. After the pertinent history and physical and risk-factor evaluation, the CFDs, CTs, MRIs, and MRAs, if available, were evaluated. At the time of review all noninvasive studies were graded for image quality as good, fair, or poor. Attending vascular surgeons, neurosurgeons, and neurologists who were unaware of the results of angiographic scans then made independent treatment decisions on the basis of the available data. The panelists also determined whether arteriography would be likely to furnish additional useful information. The angiograms then were reviewed and the management plans again recorded, including any

changes prompted by the angiograms. Panelists were not blinded to the opinions of the other panelists, but all opinions were stated in succession. In the case of differing opinions, each panelist's opinion was recorded along with the management decision made after arteriography. The same panel reviewed all University of Arizona and Tucson VA cases. The Denver VA cases were reviewed by a different panel with the same methods. The Arizona panel reviewed the Denver VA results and decided that all decisions were appropriate.

RESULTS

All 103 patients underwent CFD and cerebral angiography. Additional noninvasive tests included CT, MRI, and MRA in 50%, 56%, and 48% of patients, respectively. Only 4% of CFDs, 2% of CTs, 3% of MRIs, 16% of MRAs, and 2% of angiograms were graded as of fair or poor quality; the remainder were graded as good.

Brain imaging, including CT and MRI, did not disclose any unsuspected disease, such as mass lesions, aneurysm, or arteriovenous malformation. CT often showed normal results in patients with acute stroke. Intracranial hemorrhage was not noted in any patient. MRI was better at showing deep white matter changes. Brain imaging did not alter clinical management in any case.

The correlation of arteriography with CFD was excellent ($\kappa = 0.716 \pm 0.04$). The usual areas of disagreement were in patients with moderate stenoses. In this group CFD tended to lead to a slightly greater estimate of the degree of stenosis than did arteriography.

Overall, cerebral angiography altered the management of patients who were being evaluated for cerebrovascular disease 11% of the time (Fig. 1). In 73 patients operative indications, symptoms, and CFD findings were consistent, and the panel felt comfortable proceeding with operative or medical therapy without angiography. In this subgroup of patients, angiography changed management in only one patient, in whom angiography revealed only an S-curve in the carotid rather than a high-grade stenosis. MRA concurred with CFD findings in 92% of studies, but did not alter management in any patient.

After review of noninvasive studies, 30 of the 103 patients (29%) were believed to require arteriography before a confident clinical decision could be made. Indications for angiography in these 30 patients are listed in Table I. Arteriography was believed necessary only in five asymptomatic patients and was always the result of uncertainty regarding the degree of stenosis

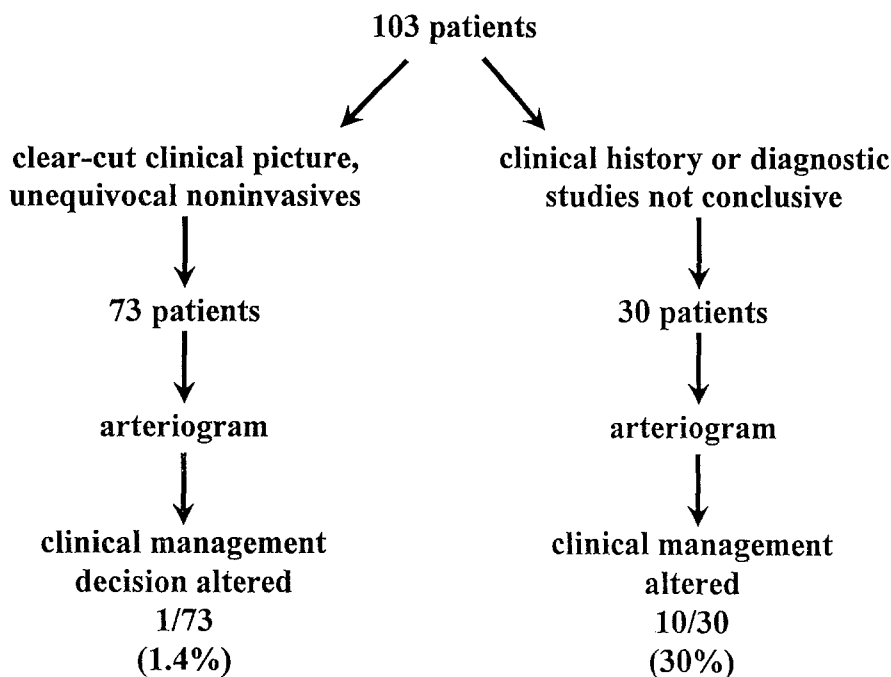


Fig. 2. Influence of arteriography on clinical management based on whether panel decided that clinical history and noninvasive tests were compatible and conclusive.

or to confirm occlusion shown by CFD. The other 25 patients had symptomatic cerebrovascular disease. In 10 of the 30 patients (33%) management decisions were changed on the basis of angiogram results (Fig. 2). In six patients, medical therapy was chosen rather than operative therapy because angiography downgraded the severity of the stenosis. In four patients, operative therapy was recommended rather than medical therapy because angiography revealed severe ulceration (two patients), or a high-grade ICA stenosis that had been considered occluded because of CFD results (two patients). Both patients with false positive findings of carotid occlusion by CFD also underwent MRA. Although one of these MRAs did demonstrate a string sign, the other was of poor quality and was nondiagnostic. In only three categories in Table I did angiography actually alter management decisions. These categories were patients with 50% to 79% stenoses by CFD with confounding variables, those with high-grade stenoses contralateral to a carotid occlusion, and those who required confirmation of an occluded internal carotid artery. Two patients had demonstration of intracranial aneurysms that were elected to be followed conservatively. Only two patients were found to have significant aortic arch lesions. One was a patient with recurrent carotid disease in whom the high-grade recurrent carotid stenosis was repaired, but who was believed to

be too high a risk for further procedures. Proximal disease was suspected in the second patient on the basis of CFD findings; the patient underwent a carotid-to-carotid bypass procedure with concomitant carotid endarterectomy.

DISCUSSION

Cerebral arteriography has been an essential component of the preoperative evaluation of patients being considered for carotid endarterectomy ever since the operation was first performed more than 40 years ago. In the early years of carotid surgery no alternatives to arteriography existed, but over the last decade CFD, and more recently MRA, have emerged as useful noninvasive tests to determine the presence of and quantitate the severity of carotid bifurcation disease.

Although some investigators have cautiously suggested that angiography may be safely omitted in selected patients with unequivocal noninvasive studies,¹¹⁻¹⁵ others have insisted that cerebral arteriography remain a mandatory preoperative study.^{8,19,26} To our knowledge, only one published study has prospectively evaluated the additional contribution of arteriography to carefully performed noninvasive tests (duplex scanning) in a large series of patients. Dawson and associates¹¹ evaluated 103 consecutive patients who were being considered for carotid en-

Table I. Indications in 30 patients who required cerebral arteriography

| <i>Indication</i> | <i>No. of patients</i> | <i>No. whose management changed based on angiography findings</i> |
|--|------------------------|---|
| 50% to 79% stenosis by duplex scan with confounding variables such as unclear symptoms, question of ulceration, or poor operative risk | 10 | 6 |
| High-grade stenosis opposite carotid occlusion | 8 | 2 |
| Suggestion of non-atherosclerotic disease | 4 | 0 |
| Confirm occlusion | 3 | 2 |
| Suggestion of proximal disease | 2 | 0 |
| Vertebrobasilar workup indicated | 2 | 0 |
| Suboptimal noninvasive studies | 1 | 0 |

endarterectomy who underwent both CFD and cerebral angiography and concluded that clinical assessment and CFD were sufficient for the preoperative evaluation of 93% of operative candidates.

Advocates of routine preoperative cerebral arteriography cite the following reasons: (1) to detect incidental intracranial aneurysms; (2) to detect intracranial carotid and middle cerebral artery stenosis; (3) a disappointing correlation was found between CFD and arteriography in several studies; and (4) "no study proving benefit of endarterectomy compared with a nonsurgical randomized cohort has been conducted using only ultrasonographic evaluations."²⁶ The benefits of angiography are thought to outweigh the 0.4% to 1% risk of angiogram-induced stroke.²⁶

Advocates of a more limited or selective use of cerebral arteriography question both the considerable expense associated with the procedure and the risk of significant complications, which include a mortality rate of 0.1% and a stroke risk of 1% to 4%. In the recently reported ACAS, 50% of the strokes in the group that was randomized to surgery occurred as a result of arteriography.³ Many investigators also have questioned the clinical significance of the additional information provided by arteriography and the frequency with which it alters clinical decisionmaking. Intracranial aneurysms were identified in 39 of the 1500 cerebral arteriograms obtained as part of NASCET, yet only six (0.4%) were deemed clinically important.²⁶ Likewise, although CFD does not detect carotid siphon or intracranial arterial stenoses, such lesions do not appear to be a contraindication to carotid endarterectomy for high-grade stenosis. Mattos et al.²⁷ demonstrated severe siphon stenoses in less than 5% of patients. In addition, the presence of such lesions has not been found to increase either early or late neurologic morbidity after carotid endarterectomy.²⁸ Concern over missed proximal brachioce-

phalic lesions also appears to be unwarranted. Akers et al.²⁹ reviewed 1000 arch aortograms and identified significant intrathoracic arterial stenoses in only 1.8%, most of which were suspected on physical examination; none of the lesions that required surgery would have been missed if routine arteriography had been omitted.

Concerns about the accuracy of CFD have led some investigators to state that reliance on such studies is a "dubious presurgical strategy."²⁶ It is important to note, however, that although many of the larger clinical trials relied heavily on arteriography, the CFD examinations frequently suffered from lack of standardization and quality control.³⁰ It is undeniable that in established vascular laboratories with well-trained personnel and ongoing quality control the accuracy of CFD approaches or exceeds 90% in the identification of >50% internal carotid stenoses.^{8,14} Moneta et al.²⁵ recently published duplex criteria that correlate well with NASCET angiographic criteria for >70% stenosis.

Numerous investigators have begun to cautiously advocate carotid endarterectomy on the basis of noninvasive studies alone.¹¹⁻¹⁴ Mattos et al.¹⁴ reviewed 167 patients who underwent both CFD and carotid arteriography and reported that arteriography altered management in only 4% of patients. Although other investigators have corroborated these data, the evolution of a new technique, MRA, has led to the recommendation that CFD be followed by MRA. If the latter study confirms the CFD findings, it has been suggested that conventional arteriography may then be safely omitted. Polak et al.³¹ and Turnipseed et al.^{32,33} reported that with this combined approach, arteriography will be required in only 12% to 21% of patients. Although the performance of MRA may provide an added level of comfort by offering the clinician images that superficially resemble those from

conventional arteriograms, whether MRA offers any additional clinically useful information with sufficient frequency to justify its routine use is unclear.

The controversies and uncertainties outlined above led us to prospectively study CFD, arteriography, and MRA in the evaluation of 103 candidates for carotid endarterectomy. Although all patients underwent both CFD and conventional arteriography, only 48% were also studied with MRA. In the 70% of patients who had a clear-cut clinical picture and good-quality noninvasive studies, the arteriogram changed the clinical decision to operate in only one instance. In the other 30%, however, further information in the form of arteriography was desired. In this subgroup, the clinical decision was altered one third of the time. The most common situations in which management was altered were in six patients with 50% to 79% stenoses and atypical symptoms, in two patients with bilateral high-grade lesions on CFD, and in two patients in whom carotid occlusion was suggested by CFD but in whom string signs also were identified by conventional arteriography. The current MRA technology does not appear to produce images of sufficient quality to obviate arteriography, with the possible exception of ruling out pseudo-occlusion. Also, the aortic arch and supraaortic trunks cannot be reliably demonstrated.

On the basis of this experience, we suggest that clinical evaluation and quality CFD are sufficient to evaluate approximately 70% of candidates for carotid endarterectomy. Such an approach is conservative, minimizes patient risk and diagnostic errors, and would result in significant cost savings. It is probably unrealistic to perform carotid endarterectomy in all symptomatic patients with >50% internal carotid artery stenosis by CFD as advocated by Dawson et al.,¹¹ particularly in light of NASCET and ECST, which demonstrated the benefit of carotid endarterectomy only for stenoses >70%.^{1,2} Until further data are available we believe angiography to be helpful in making clinical decisions in many patients in whom CFD showed 50% to 70% lesions.

Table II delineates the Medicare costs involved in the preoperative evaluation of carotid surgery patients with three possible scenarios: (1) the current standard approach (CFD and arteriogram in all patients); (2) CFD and MRA in all patients, with arteriogram in 20%³¹; and (3) initial CFD with selective arteriography in 30% of patients, as recommended on the basis of our data. The data were calculated with appropriate CPT codes and actual Medicare reimbursement figures at University Medical Center (Tucson, Ariz.) rather than billed charges, which tend to overestimate

Table II. Cost analysis: medicare reimbursement evaluation of 100 consecutive patients

| <i>Duplex scan and arteriography in all patients (100)</i> | <i>\$191,500</i> |
|--|------------------|
| Duplex scan and MRA (100) | 63,531 |
| Selective arteriography (20) | 35,100 |
| | \$98,631 |
| Duplex scan (100) | 16,000 |
| Selective arteriography (30) | 52,650 |
| | \$68,650 |

true costs. The approach recommended here (initial CFD with selective arteriography in 30% of patients) would save almost \$125,000 for the evaluation of every 100 candidates for carotid endarterectomy.

The performance of carotid endarterectomy without angiography mandates the use of a well-equipped vascular laboratory with well-trained personnel and an established quality control record with correlation of CFD and angiographic findings based on extensive experience. Cut-off points for specific degrees of stenosis should be established by each vascular laboratory. Because a small but significant portion of patients will still require arteriography, the laboratory should maintain an ongoing protocol to correlate angiographic and CFD findings to assure continued diagnostic accuracy. Absolute indications for conventional arteriography include: to confirm internal carotid artery occlusion; the suggestion on noninvasive studies that disease is not limited to the carotid bifurcation (inability to visualize normal ICA above the stenosis or the suspicion of hemodynamically significant proximal disease); and to evaluate patients with nonatherosclerotic disease. Relative indications for arteriography include patients with recurrent carotid stenosis, patients with contralateral occlusion, and patients with severe bilateral disease.

With the rapid development of high-quality, approved vascular laboratories and an ever-increasing emphasis on cost control and the streamlining of patient care, we suspect that treatment algorithms based primarily on clinical findings and CFD will be applied more widely across the country. It is incumbent on those who advocate such an approach to demand rigid standards of vascular laboratory quality control and accuracy.

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