Determination of sixty percent or greater carotid artery stenosis by duplex Doppler ultrasonography

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Purpose: **The Asymptomatic Carotid Atherosclerosis Study, demonstrating the benefit of carotid endarterectomy for symptom-free patients with 60% or greater carotid artery stenosis, has given rise to the need for development of screening parameters for detection of these lesions. Traditional duplex categories (50% to 79%, 80% to 99%) are not applicable. We sought to develop duplex criteria for determination of 60% or greater carotid artery stenosis by comparison with arteriography.**

Methods: **The duplex scans and arteriograms of 110 patients (210 carotid arteries), obtained within 1 month of each other, were reviewed by blinded readers. Arteriographic stenosis was determined by the method of the Asymptomatic Carotid Atherosclerosis Study. Duplex measurements of peak systolic velocity (PSV) and end-diastolic velocity (EDV) were recorded, and ratios of velocities in the internal and common carotid arteries (ICA, CCA) were calculated. Sensitivity, specificity, positive and negative predictive values (PPV, NPV), and accuracy were determined, and receiver-operator characteristic curves were generated.**

Results: **Interobserver agreement for measurement of arteriographic stenosis was "almost perfect" (kappa = 0.86). The criteria determined for detection of 60% or greater stenosis were as follows: $PSV_{ICA} > 170$ cm/sec (sensitivity 98%, specificity 87%, PPV 88%, NPV 98%, accuracy 92%), $EDV_{ICA} > 40$ cm/sec (sensitivity 97%, specificity 52%, PPV 86%, NPV 86%, accuracy 86%), $PSV_{ICA}/PSV_{CCA} > 2.0$ (sensitivity 97%, specificity 73%, PPV 78%, NPV 96%, accuracy 76%), $EDV_{ICA}/EDV_{CCA} > 2.4$ (sensitivity 100%, specificity 80%, PPV 88%, NPV 100%, accuracy 88%). If all of the above criteria were met, 100% accuracy was achieved.**

Conclusion: **It is concluded that 60% or greater carotid artery stenosis can be reliably determined by duplex criteria. The use of receiver-operator characteristic curves allows the individualization of duplex criteria appropriate to specific clinical situations of patient screening for lesions (high sensitivity and NPV) or use as a sole preoperative imaging modality (high PPV). Individual vascular laboratories must validate their own results.**
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The investigators of the Asymptomatic Carotid Atherosclerosis Study (ACAS) recently reported interim results of a randomized controlled clinical trial of carotid endarterectomy in patients with asymptomatic carotid artery stenosis of 60% or greater reduction in diameter.[1] Carotid endarterectomy was found to be beneficial when compared with aggressive medical treatment of these patients. Physicians participating in the study and the general medical community were notified of these results and advised to reevaluate patients who had not undergone surgery.

Duplex scanning is generally regarded as the most accurate noninvasive diagnostic screening modality for evaluation of carotid artery stenosis. The most commonly used criteria for determination of carotid artery stenosis rely on measurements of Doppler scanning–determined velocity data and spectral analysis. Traditional criteria categorize the carotid bifurcation as normal, 1% to 15% stenosis, 16% to 49%

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stenosis, 50% to 79% stenosis, 80% to 99% stenosis, and complete occlusion.[2] These categories, however, are not applicable for determination of 60% or greater carotid artery stenosis.

The ACAS study determined arteriographic carotid artery stenosis by comparing the carotid minimal residual lumen (MRL) and distal lumen diameters,[3] the method recommended by the Ad Hoc Committee on Reporting Standards, Society for Vascular Surgery/North American Chapter, International Society for Cardiovascular Surgery,[4] and also used in the Veterans Affairs (VA) Cooperative Trial[5] and North American Symptomatic Carotid Endarterectomy Trial (NASCET),[6] commonly referred to as the NASCET method of determination of carotid artery stenosis. We sought to develop duplex Doppler ultrasound criteria for determination of 60% or greater carotid artery stenosis by comparison with arteriography with this arteriographic method of measuring stenosis.

PATIENTS AND METHODS

Patients. Between January 1992 and January 1994, 110 patients were identified who had undergone both duplex scanning and carotid angiography at the Hospital of the University of Pennsylvania within 1 month of each other (210 carotid arteries). These patients were being evaluated for surgical treatment of carotid artery atherosclerosis and represent all patients during this interval who had complete arteriographic examinations and duplex scanning data available for review.

Arteriography. Percutaneous catheter arteriograms were obtained in all patients with at least two-view or, in most cases, four-view biplane selective common carotid arteriograms. Carotid arteriography was performed with either standard cut-film techniques or with the use of high-resolution digital subtraction imaging (1024 × 1024 matrix).

The percent stenosis, determined by arteriography, was calculated from direct measurements of the maximum stenosis (MRL) in the carotid bifurcation region (distal common carotid artery [CCA] and proximal internal carotid artery [ICA]) made by use of a hand-held magnifier marked in 1 mm increments. This was compared with the diameter of the normal-appearing ICA distal to the bifurcation (DL), with the technique described for the ACAS[3] and NASCET[6] studies. Diameter stenosis was calculated by use of the MRL and DL in the equation: $1 - (MRL/DL)] \times 100$.

Observers were blinded both to the results of the duplex study and to the other observers' readings. The first 70 vessels were evaluated by three blinded readers, and an interim calculation of interobserver agreement was made. Owing to the "near perfect" agreement of the three observers (see Results), a single observer completed the remaining 140 carotid arteries, providing a total of 210 carotid arteries for evaluation with complete duplex and arteriographic data.

Duplex Doppler ultrasonography. Duplex Doppler ultrasound studies were performed on a Hewlett-Packard Sonos 1000 Color Duplex System (Andover, Mass.) with a 7.5 MHz linear array transducer with 5.6 MHz Doppler frequency. The entire cervical, common, internal, and external carotid arteries were examined. Velocity waveforms were obtained routinely from the CCA at the base of the neck, just proximal to the carotid bifurcation, the proximal, mid, and distal ICA, and the external carotid artery. In addition, velocity waveforms were obtained from any location where stenosis was suspected by either B-mode appearance or color-flow mapping. The highest peak systolic velocity (PSV) and end-diastolic velocity (EDV) were recorded from each location.

Analysis. Maximum PSV and EDV in the carotid bifurcation region (distal CCA or ICA, PSV_{ICA}, EDV_{ICA}) was used for comparison with maximal angiographic stenosis. The maximal carotid bifurcation PSV_{ICA} and EDV_{ICA} were compared with the maximal PSV or EDV in the proximal CCA low in the neck (PSV_{CCA}, EDV_{CCA}), and their ratios were (PSV_{ICA}/PSV_{CCA}, EDV_{ICA}/EDV_{CCA}) calculated. Receiver-operator characteristic (ROC) curves were generated to predict a 60% or greater angiographic stenosis. These curves describe sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of each criterion (PSV_{ICA}, EDV_{ICA}, PSV_{ICA}/PSV_{CCA}, EDV_{ICA}/EDV_{CCA}).

Interobserver variability for interpretation of arteriographic stenosis was assessed with the kappa (κ) statistic, in which the degree of agreement between different readers was defined by the scale of Landis and Koch:[7] less than 0.00, poor; 0.00 to 0.20, slight; 0.21 to 0.40, fair; 0.41 to 0.60, moderate; 0.61 to 0.80, substantial; and 0.81 to 1.0, almost perfect. The categories of comparison for this calculation were as follows: 0% to 49% stenosis, 50% to 59% stenosis, 60% to 69% stenosis, 70% to 79% stenosis, 80% to 89% stenosis, 90% to 99% stenosis, 100% occlusion.

RESULTS

Two hundred ten carotid arteries were available for evaluation. A 60% or greater arteriographic stenosis was present in 97 (46%) cases, not including 17 (8%) occluded internal carotid arteries. Interobserver variability for the first 70 carotid arteries selected at random and evaluated by three observers was "almost perfect" ($\kappa = 0.86$).

Plots of sensitivity, specificity, PPV, NPV, and accuracy for various values of the PSV_{ICA}, EDV_{ICA}, PSV_{ICA}/PSV_{CCA}, and EDV_{ICA}/EDV_{CCA} are shown in Figs. 1 through 4. Suggested criteria for determination of 60% or greater carotid artery stenosis are shown in Table I.

PSV_{ICA} (Fig. 1). The greatest accuracy of PSV_{ICA} for prediction of a 60% or greater arteriographic stenosis was noted at PSV_{ICA} greater than 170 cm/sec (accuracy 92%). At this cut point there was also high sensitivity (98%) and NPV (98%). Beyond this level, sensitivity and NPV declined with only a slight increase in specificity and PPV.

EDV_{ICA} (Fig. 2). An EDV_{ICA} greater than 40 cm/sec yielded high accuracy (86%), sensitivity (97%), and NPV (86%). At higher EDV_{ICA} the sensitivity and NPV declined, although there was a slight increase in accuracy as a result of fewer false-positive results. The highest accuracy of EDV_{ICA} as a predictor of 60% or greater carotid arteriographic stenosis was noted at EDV_{ICA} greater than 60 cm/sec (accuracy of 92%). This higher accuracy is at the cost of lower sensitivity (94%) and NPV (83%).

PSV_{ICA}/PSV_{CCA} (Fig. 3). A ratio greater than 2.0 provided high sensitivity (97%) and NPV (96%), but somewhat lower specificity (73%) and PPV (78%) with an overall accuracy of 76%. The maximum accuracy obtainable with the PSV ratio was a ratio greater than 2.8 (90%). This accuracy is achieved at the cost of decreased sensitivity (90%) and NPV (90%).

EDV_{ICA}/EDV_{CCA} (Fig. 4). A ratio greater than 2.4 provided a sensitivity of 100%, specificity of 80%, PPV of 88%, and NPV of 100% with an overall accuracy of 88%. At higher ratios, sensitivity and NPV are decreased without a significant increase in accuracy.

Combined criteria. When all four criteria for 60% or greater stenosis are met ($PSV_{ICA} > 170$ cm/sec, $EDV_{ICA} > 40$ cm/sec, $PSV_{ICA}/PSV_{CCA} > 2.0$, $EDV_{ICA}/EDV_{CCA} > 2.4$), an accuracy of 100% can be achieved with sensitivity, specificity, PPV, and NPV of 100% each. Of the 97 carotid arteries with 60% or greater stenosis, 67 (69%) met all four criteria.

DISCUSSION

The recently published ACAS trial demonstrated the benefit of carotid endarterectomy for symptom-free patients with 60% or greater carotid artery stenosis.[1] Because these patients are symptom free, a screening protocol must be implemented. The most widely used screening modality for determination of carotid artery stenosis is duplex Doppler ultrasonography; the need for accurate criteria for determination of 60% or greater carotid artery stenosis by duplex scanning is apparent.

A great many parameters for determination of carotid artery stenosis by duplex scanning have been developed over the years. Prominent among these are traditional categories of carotid artery stenosis, which include a single category for carotid artery lesions of 50% to 79% diameter reduction.[2] In the validation studies that produced this traditional category, determination of carotid artery stenosis was not based on the minimal residual lumen formula used in the ACAS,[3] NASCET,[6] and VA Cooperative Trials.[5] Rather they were based on an alternative method that employed the ratio of residual lumen used to estimated normal bulb diameter, the method of the European Carotid Surgery Trial.[8] This latter method results in a significant "overestimation" of carotid artery stenosis by comparison with the ACAS, NASCET, and VA Cooperative Trial methods. An 80% to 99% stenosis by the bulb estimated diameter reduction method correlates with an approximately 55% to 75% stenosis by the method that compares minimal residual bulb lumen with the distal cervical carotid. The importance of the method of measurement of angiographic carotid artery stenosis with respect to development of duplex scanning criteria has been emphasized by several authors.[9-12] Standard criteria have been suggested by the Committee on Standards for Noninvasive Testing of the Joint Council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery,[4] who have recommended that the MRL method used in the ACAS, NASCET, VA Cooperative Trials, and this study be adopted. It is imperative that correlation between results of randomized trials and duplex scanning parameters be based on the same gold standard angiographic criteria.

The use of ROC curves is a helpful technique for developing appropriate duplex scanning criteria. We

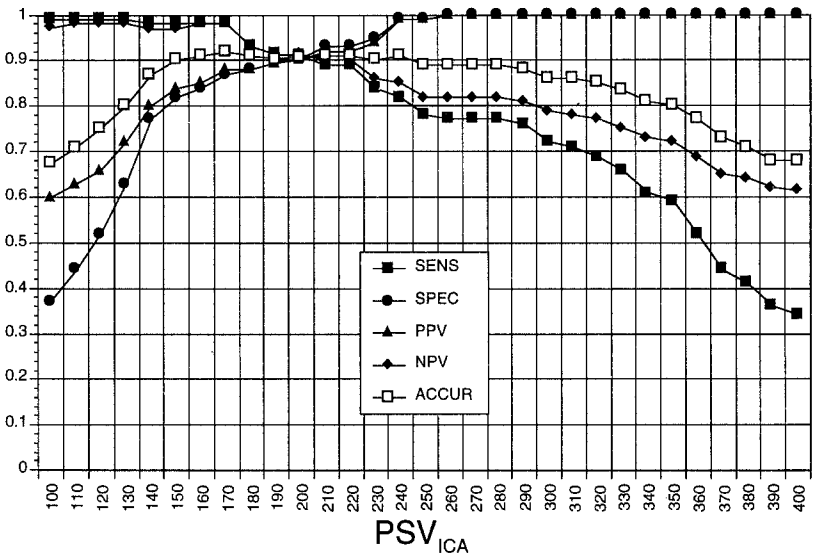

Fig. 1. PSV_{ICA} determination of 60% or greater carotid artery stenosis. PSV_{ICA} greater than 170 cm/sec provided high sensitivity (98%) and NPV (98%) and is appropriate for use as screening parameter. PSV_{ICA} greater than 230 cm/sec may be more appropriate if duplex scanning is to be used as sole preoperative imaging modality, owing to lower false-positive rate (PPV) = 94%).

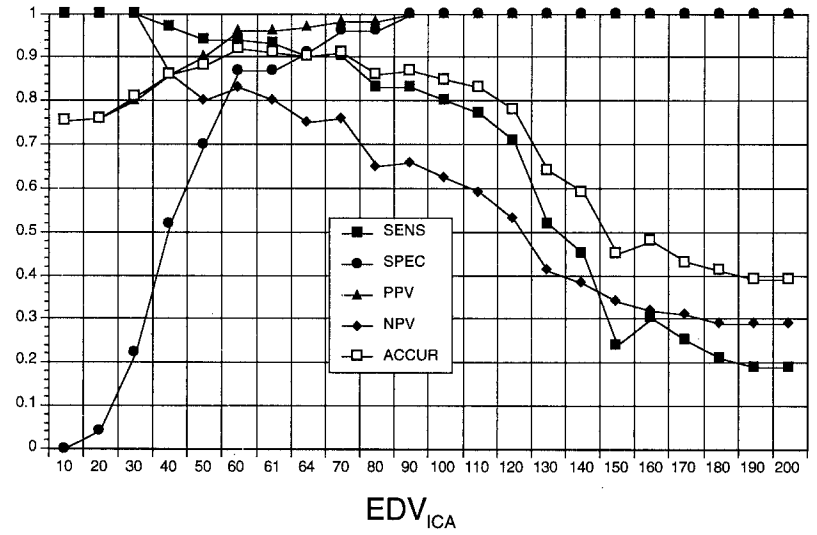

Fig. 2. EDV_{ICA} greater than 40 cm/sec provides high sensitivity (97%) and NPV (86%) and is appropriate for use as screening parameter. If duplex scanning is to substitute for arteriography, EDV_{ICA} greater than 60 cm/sec provides lower false-positive rate (PPV = 96%).

applied this technique to the cardinal duplex Doppler measurements of PSV, EDV, and the ratios of PSV and EDV in the ICA and CCA. In choosing precise cut points, however, tradeoffs need to be made between the PPV and NPV of the test; as the test becomes more specific, it becomes less sensitive. In choosing criteria therefore one must decide whether the most important goal is to avoid missing a patient with a significant lesion (which may engender some unnecessary confirmatory arteriograms) or to have a high PPV even at the cost of missing a number of patients with significant lesions. In a center where confirmatory arteriography is performed with few complications, it would be reasonable to select

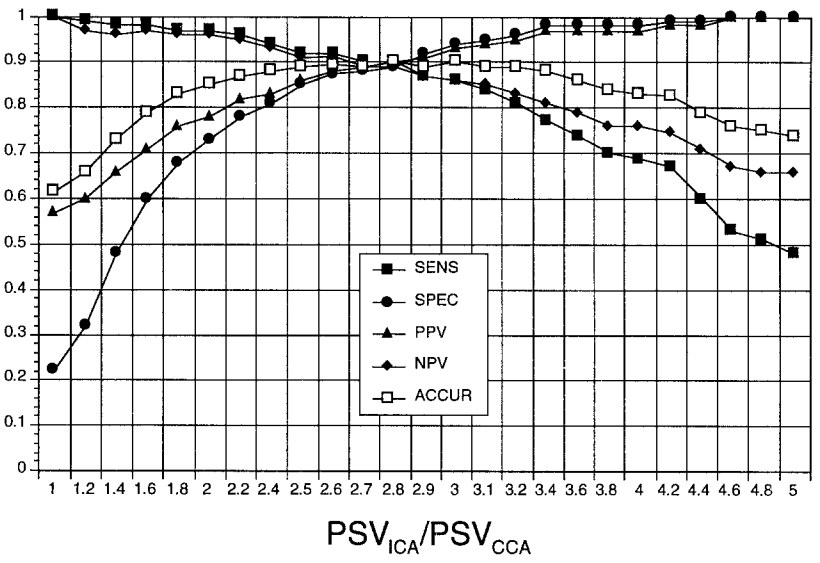

Fig. 3. PSV_{ICA}/PSV_{CCA} determination of 60% or greater carotid artery stenosis. PSV_{ICA}/PSV_{CCA} greater than 2.0 provides high sensitivity (97%) and NPV (96%) for use as screening test. False-positive rate, however, is high (22%). Higher ratio provides increased PPV.

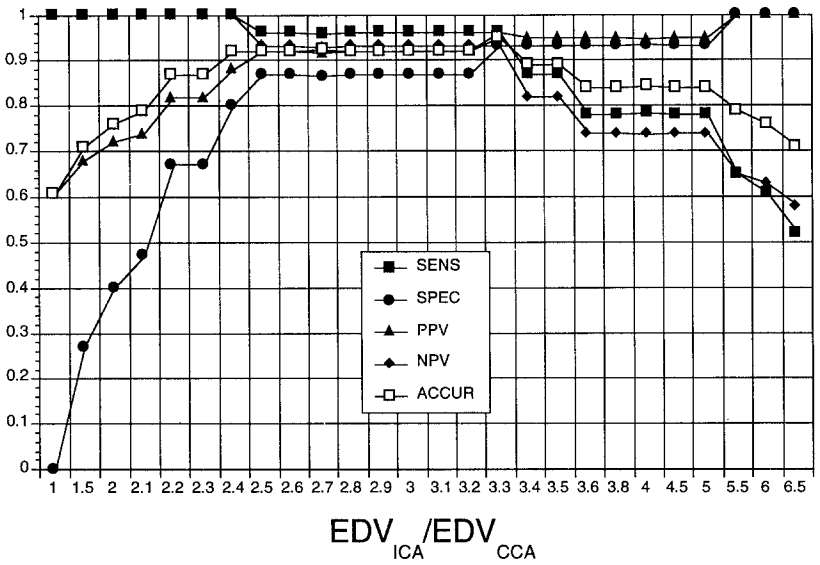

Fig. 4. EDV_{ICA}/EDV_{CCA} determination of 60% or greater carotid artery stenosis. EDV_{ICA}/EDV_{CCA} provides perfect (100%) sensitivity and NPV, but significant false-positive rate (12%). Curves are relatively "flat" beyond ratio of 2.5.

parameters offering a maximal sensitivity and NPV to avoid missing patients who have significant disease. On the other hand, if one wishes to perform surgery on the basis of the duplex scanning result alone,[13-17] one would prefer to have a high PPV to avoid operating on patients who do not fulfill the criteria of the randomized trials. Thus the duplex criteria chosen should be tailored to the specific institutional and individual situation.

Of the four criteria examined, PSV_{ICA} greater than 170 cm/sec offers the greatest overall accuracy (92%) for determination of a 60% or greater carotid artery stenosis. This provides a high sensitivity (98%) and NPV (98%) and would be well suited for use as

Table I. Suggested criteria for determination of 60% or greater carotid artery stenosis

Criterion	*Sensitivity*	*Specificity*	*PPV*	*NPV*	*Accuracy*
PSV_{ICA} >170	98%	87%	88%	98%	92%
EDV_{ICA} >40	97%	52%	86%	86%	86%
PSV_{ICA}/PSV_{CCA} >2	97%	73%	78%	96%	76%
EDV_{ICA}/EDV_{CCA} >2.4	100%	80%	88%	100%	88%
All above criteria met	100%	100%	100%	100%	100%

a screening test. However, if one were to choose a criterion of PSV_{ICA} for selection of patients for operation without confirmatory arteriography, a higher PSV would be appropriate to decrease the false-negative rate (12% at PSV_{ICA} greater than 170 cm/sec). A PSV_{ICA} greater than 230 cm/sec provides a PPV of 94% with a sensitivity of 89%.

The ACAS investigators chose the approach of high PPV as an entry point into the trial, requiring "duplex ultrasonography showing a peak systolic frequency or end-diastolic frequency greater than the machine-specific cut point with predicted false-positive rate of 5% determined by correlation of Doppler flow velocities with arteriography in 50 consecutive cases."[1] The necessity of high PPV as an entry criterion into a clinical trial is obvious. It also should be the preeminent criterion if confirmatory arteriography is not to be performed before surgical intervention.

EDV is useful for severe stenoses where "aliasing" is occasionally problematic for determination of PSV. For use as a screening test, EDV_{ICA} greater than 40 cm/sec provides high sensitivity (97%) and NPV (86%). If duplex scanning is to be used as a substitute for arteriography, an EDV_{ICA} greater than 60 cm/sec provides a high PPV (96%) while still maintaining high sensitivity (94%), but the NPV decreases to only 83%.

Ratios of PSV and EDV are useful for overcoming variability in isolated PSV and EDV measurements as a result of changes in blood pressure and hemodynamic effects of contralateral stenoses or occlusions, as well as ipsilateral tandem lesions. A PSV_{ICA}/PSV_{CCA} ratio greater than 2.0 and an EDV_{ICA}/EDV_{CCA} ratio greater than 2.4 provide high sensitivity and NPV and are appropriate for use as screening test parameters. A higher ratio provides an increase in PPV for the PSV ratio, but the EDV ratio presents a relatively flat ROC curve from a ratio of 2.5 through 5.0.

The presence of all four criteria as positive for a given carotid artery ensures the presence of a 60% or greater lesion with perfect accuracy and was achieved in 69% of cases of 60% or greater carotid artery stenosis. These criteria differ only slightly from previously published duplex criteria for determination of 60% or greater carotid artery stenosis.[18]

A recent report of a multicenter validation study of Doppler ultrasonography versus angiography demonstrated alarming variability in PSV measurement of the same lesion ($\geq$60% carotid artery stenosis by arteriography) between various devices and institutions.[19] The cut point for determination of a 60% or greater angiographic stenosis to ensure a PPV of 90% ranged from 151 to 390 cm/sec. This study highlights the interinstitutional variability, as well as the variability between machines at the same institution. It is essential therefore that each individual institution and perhaps each individual sonographer and machine establish criteria for determination of carotid artery stenosis, validated against the gold standard of arteriography. We believe the use of registered vascular technologists and participation in the certification process of the Intersocietal Commission for the Accreditation of Vascular Laboratories to be helpful in this regard. The actual duplex criteria selected should be tailored to the application. Once the ROC curve is established, criteria appropriate for use as either a broad screening test (with high sensitivity and NPV) or as a sole preoperative imaging modality before surgery (high PPV) may be selected.

REFERENCES

1. National Institute of Neurological Disorders and Stroke. Clinical advisory: carotid endarterectomy for patients with asymptomatic internal carotid artery stenosis. Stroke 1994; 25:2523-4.
2. Roederer GO, Langlois YE, Chan ATW, et al. Ultrasonic duplex scanning of the extracranial carotid arteries: improved accuracy using new features from the common carotid artery. J Cardiovasc Ultrasonography 1982;1:373-80.
3. Asymptomatic Carotid Atherosclerosis Study Group. Study design for randomized prospective trial of carotid endarterectomy of asymptomatic atherosclerosis. Stroke 1989;20: 844-9.
4. Thiele BL, Jones AM, Hobson RW, et al. Standards in noninvasive cerebrovascular testing: report from the Committee on Standards for Noninvasive Vascular Testing of the Joint Council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery. J VASC SURG 1992;15:495-503.

5. Veterans Administrative Cooperative Trialists. Role of carotid endarterectomy in asymptomatic carotid stenosis. Stroke 1986;17:534-8.
6. 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.
7. Landis JR, Koch GG. The measurement of observer agreement for categorical data. Biometrics 1977;33:159-74.
8. European Carotid Surgery Trialist's Collaborative Group. MRC European Carotid Surgery Trial: interim results for symptomatic patients with severe (70% to 99%) or with mild (0% to 29%) carotid stenosis. Lancet 1991;337:1235-43.
9. Moneta GL, Edwards JM, Chitwood RW, et al. Correlation of North American Symptomatic Carotid Endarterectomy Trial (NASCET) angiographic definition of 70-99% internal carotid artery stenosis with duplex scanning. J VASC SURG 1993;17:152-9.
10. Neale ML, Chambers JL, Kelly AT, et al. Reappraisal of duplex criteria to assess significant carotid stenosis with specific reference to reports from the North American Symptomatic Carotid Endarterectomy Trial and the European Carotid Surgery Trial. J VASC SURG 1994;20:642-9.
11. Fox AJ. How to measure carotid stenosis. Radiology 1993; 186:316-8.
12. Alexandrov AV, Bladin CF, Maggisano R, et al. Measuring carotid stenosis: time for a reappraisal. Stroke 1993;24: 1292-6.
13. Gelabert HA, Moore WS. Carotid endarterectomy without angiography. Surg Clin North Am 1990;70:213-23.
14. Moore WS, Ziomek S, Quiñones-Baldrich WJ, et al. Can clinical evaluation and noninvasive testing substitute for arteriography in the evaluation of carotid artery disease? Ann Surg 1988;208:91-4.
15. Wagner WH, Treiman RL, Cossman DV, et al. The diminishing role of diagnostic arteriography in carotid artery disease: duplex scanning as definitive preoperative study. Ann Vasc Surg 1991;5:105-10.
16. Gertler JP, Cambria RP, Kistler JP, et al. Carotid surgery without angiography: noninvasive selection of patients. Ann Vasc Surg 1991;5:253-6.
17. Mittl RL, Broderick M, Carpenter JP, et al. Blinded-reader comparison of magnetic resonance angiography and duplex ultrasonography for carotid artery bifurcation stenosis. Stroke 1994;25:4-10.
18. Bluth EI, Stavros AT, Marich RW, et al. Carotid duplex sonography: a multicenter recommendation for standardized imaging and Doppler criteria. Radiographics 1988;8:487-506.
19. Howard G, Chambless LE, Baker WH. A multicenter validation study of Doppler ultrasound versus angiogram. J Stroke Cerebrovasc Dis 1991;1:166-73.

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DISCUSSION

Dr. Patrick J. Lamparello (New York, N.Y.). Two recent prospective randomized studies, the ACAS study and the Veterans Administration Asymptomatic Carotid Artery Trials, have confirmed that carotid endarterectomy for asymptomatic carotid artery stenosis reduces the risk of stroke when compared with medical therapy. The benefits of carotid artery surgery in symptom-free patients have previously been based on retrospective reviews and a surgeon's experience. The question now before us is at what degree of stenosis is carotid artery surgery of benefit? The ACAS study used 60% stenosis. The VA Trial showed a decrease in adverse neurologic events when greater than 50% carotid artery stenosis was used as criteria for surgery.

Dr. Carpenter and his colleagues have studied this problem and have identified duplex scanning criteria that can reliably determine whether a patient has greater than 60% stenosis. Duplex scanning was picked because it is obviously the best screening test currently available. The study identifies the criteria that are applicable to vascular laboratories. The authors also plead that each laboratory should do its own validation studies, and, indeed, at New York University we have found similar results when Dr. Carpenter's criteria are used.

In 1994 our vascular surgical group at New York University examined the operative risks and long-term results of carotid endarterectomy for symptom-free patients in terms of stroke, death, and recurrent stenosis. This represents a consecutive series of patients who underwent carotid endarterectomy from 1983 to 1988. Note that approximately 20% or 100 of these patients were symptom free at the time of surgery. These 100 consecutive patients were chosen for the long-term follow-up and served as a basis of our report.

One hundred sixteen carotid endarterectomies were performed. One hundred eleven had greater than 70% diameter reduction at the carotid bifurcation according to duplex scanning with arteriographic confirmation. Five had less stenosis, but marked irregularity was present.

Noteworthy among the series was that there were no perioperative strokes or deaths among this group of patients. The life-table analysis of this group of patients shows that there is a 96% stroke-free survival rate at 5 years after endarterectomy for asymptomatic disease.

Because the results have improved for surgery on symptom-free patients, and because we now have reasonable criteria for identifying the patient with stenosis on duplex scanning, the broader question is at what degree of stenosis should carotid endarterectomy be offered to the patient. Our own view is that at approximately 80% stenosis, the benefit of carotid endarterectomy outweighs

the medical therapy. Our group is now involved in a natural history study of the patients of this intermediate 50% to 79% stenosis and believe that preliminary evaluation of our data supports this conclusion.

What is your current recommendation for performing carotid endarterectomy in the symptom-free patient?

Dr. Jeffrey P. Carpenter. None of the data I have presented address the question of who should undergo operation for asymptomatic carotid artery disease. We are all anxiously awaiting publication of the ACAS trial, which may persuade many of us to change our current indication for asymptomatic carotid endarterectomy. Presently our practice has been to operate on patients with greater than 80% stenosis. Perhaps after reading the ACAS trial we will be persuaded to operate on patients with greater than 60% stenosis, and, it is hoped, with the duplex criteria I have presented, we will be prepared to identify these patients noninvasively.

Our current follow-up recommendation is to study patients every 3 months for the first year and then twice annually after that if the asymptomatic lesion is not progressing.

Dr. John J. Ricotta (Buffalo, N.Y.). I just wanted to point out something about the 60% stenosis in the ACAS. That was not a completely arbitrary decision. It was chosen as the degree of stenosis that was universally associated with a hemodynamic change.

Everybody says they only operate on 80% stenoses – if you went back and measured those angiograms, an 80% stenosis is pretty darn tight (80% stenosis is 1 mm in most carotid arteries. I believe that if you go back and look at what you're calling an 80% stenosis, when you measure it, it's probably somewhat less than that.

Dr. Jeffrey P. Carpenter. The method of measurement of carotid artery stenosis is extremely important, and different methods have been used by different authors. This we detail in the manuscript, and other authors have addressed this question as well. The original Strandness criteria are based on an estimation of bulb diameter, whereas the NASCET, ACAS, and VA cooperative trials relied on determination of the minimal residual lumen compared with the normal distal cervical carotid lumen diameter. This latter method is recommended by the Committee on Reporting Standards of the Joint Vascular Societies.

I also want to mention that an important study that emerged from ACAS and that Dr. Ricotta coauthored, examined peak systolic velocities among the various institutions participating in ACAS. You will recall that one of the ways to enter the ACAS trial was with duplex scanning alone without the need for arteriography. A preliminary validation study was undertaken by each center in which individual centers determined the 90% PPV level of PSV for determination of a 60% stenosis. The article to which I am referring reported the range of PSVs at different institutions, which was quite broad, ranging from 151 to 390 cm/sec. This points out the need for individual validation.

Dr. Ali F. AbuRahma (Charleston, W.V.). One hundred ninety-eight of 356 arteries (64%) had 60% or greater stenosis by arteriography. We looked at both the PSV and the peak systolic frequency. The only striking difference between your findings and ours is in the end diastolic frequency or velocity. I believe you indicated that when you relied on an EDV of the ICA of 40 cm/sec, the specificity was 50%, which I presume is not very good. When the EDV was increased to 60 cm/sec, the results were much better. Our finding indicated that an end diastolic frequency of 2.5 kHz (which is equivalent to 78 cm/sec) had an overall accuracy of 89%. An overall accuracy of 89% was also achieved for the by-product of both the peak systolic frequency and the end diastolic frequency of the ICA.

Dr. Carpenter. The EDV is not as accurate as the PSV for lesser degrees of stenosis because it does not rise until a higher degree of stenosis than is necessary for an increase in the PSV. That, of course, is the logic behind the use of EDV for determination of 80% carotid artery stenosis, and it was not surprising to me that the PSV would be the more sensitive indicator for a lesser degree of stenosis.

Dr. Robert W. Hobson II (Newark, N.J.). This issue on percentage stenosis is somewhat complicated. We all need to look at Dr. Carpenter's criteria and consider adopting them, but I agree with him that each one of us is going to have to identify our own cut points as we did with the ACAS trial.

And for those who are still using University of Washington criteria, I wouldn't be too quick to exclude them if you've established their value in your laboratory. Remember that the 80% stenosis (University of Washington criteria) correlates with a 50% to 60% diameter-reducing stenosis on angiography as measured by the NASCET formula. As a result, in a good-risk patient, recommending operation at the University of Washington 80% level of stenosis should correlate with your 60% data.

An additional question relates to the patient with symptoms of a transient ischemic attack or a nondisabling stroke who has the 60% to 69% diameter-reducing stenosis on arteriography. Dr. Barnett, the NASCET principle investigator, recommends randomization of these patients to medical versus surgical treatment. How can we continue to recommend randomization of these patients, when the significant cut point (ACAS) on asymptomatic stenosis is 60%?

Dr. Carpenter. It's certainly a very confused time. My bias, of course, would be to operate on that patient rather than to randomize them, but I'm not a participant in that trial.

Speaking of Dr. Barnett and this thorny issue of measurement of carotid artery stenosis, most of you have probably read in *Stroke* his reworking of the European Carotid Surgery Trial (ECST), which of course used this

bulb-estimated diameter. And if you make a correction, as Dr. Hobson was suggesting for the bulb estimation diameter to the NASCET method, the results of the ECST and NASCET come out very similar to each other rather than disparate.

Dr. G. Richard Curl (Buffalo, N.Y.). I think you've obviously shown that we can find asymptomatic stenoses very accurately, but whom should we be screening is the question that comes up very frequently from our medical colleagues. Do you have any guidelines for that?

Dr. Carpenter. That's an interesting question, and I've started working with people from the Wharton School and the Leonard Davis Institute of Health Economics at the University of Pennsylvania to do a decision analysis on the basis of cost-effectiveness.

Dr. Robert P. Leather (Albany, N.Y.). I'd just like to offer one comment from an engineering point of view. I think we forget that the stenosis is not a perfect circle and these estimates of diameter reduction then have a fairly wide tolerance that nobody has actually established. That is to say you can say it's X ± 10%, and in some instances greater. So the so-called gold standard isn't really gold. About the only way you can get at it is to do injections of the lesion, and there you have the injection under a lesser pressure, so even that has some holes in it.

So to get back to Dr. Hobson's dilemma, I think that what we should do is establish some kind of a tolerance, and then when someone comes in at 60 instead of 70, if the tolerance turns out to be plus or minus 10, it should fit. These are far from precise. Do you have any comment on that?

Dr. Carpenter. There was a fascinating study that I'm sure everybody saw, within the last year, in which excised endarterectomy specimens were compared with duplex, MRA, and arteriography, and the modality that most closely correlated with the lesion itself was not our gold standard angiography but rather was duplex scanning. It certainly is attractive to think that a physiologic rather than a contrast-based technique may be more accurate.