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# Original Contributions

# Selection Process for Surgeons in the Asymptomatic Carotid Atherosclerosis Study

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*Background and Purpose:* **The Asymptomatic Carotid Atherosclerosis Study is a prospective, multicenter, randomized clinical trial of carotid endarterectomy for the treatment of asymptomatic hemodynamically significant stenosis. This report describes the selection process for participating surgeons in the trial.**

*Methods:* **The Surgical Management Committee established guidelines for minimal annual experience and maximum neurological morbidity and mortality for surgeons to qualify to participate in the study. For approval, a surgeon must perform at least 12 carotid endarterectomies per year. Based on a review of the surgeon's last 50 consecutive endarterectomies, the combined neurological morbidity and mortality rate must be no greater than 5% for all indications and no greater than 3% for endarterectomies performed on asymptomatic patients.**

*Results:* **One hundred sixty-four surgeons from 48 centers applied for approval: 117 were approved, 17 were rejected, and 30 were not reviewed. The 117 approved surgeons submitted a total of 5,641 endarterectomies with a combined mortality and neurological morbidity rate of 2.3% for the variety of indications for operation.**

*Conclusions:* **This overall experience with carotid endarterectomy is one of the largest series reported to date. The data from approved surgeons are well within the range of acceptable neurological morbidity and mortality rates recommended by the Stroke Council of the American Heart Association, which attests to the overall quality of the surgeons participating in the study. (*Stroke* 1991;22:1353–1357)**

The best method for managing asymptomatic, preocclusive lesions of the carotid artery has yet to be defined. The Asymptomatic Carotid Atherosclerosis Study (ACAS) was designed to determine whether patients treated with prophylactic carotid endarterectomy plus aspirin antiplatelet therapy will fare better than a control group treated with aspirin alone when the end points of hemispheric transient ischemic attack, stroke, and death are compared. The design of this prospective multicenter clinical trial has been described previously.[1]

In selecting the surgeons for participation in ACAS, the Executive Committee of ACAS recognized that there is a spectrum of results that are dependent on the competence of the surgeon as well as quality of the institution in which the surgeon practices. Recently, a committee of the Stroke Council of the American Heart Association has defined upper acceptable limits of neurological morbidity and mortality as a function of indication for carotid endarterectomy.[2] Because it is recognized that the outcome of a study comparing the results of prophylactic carotid endarterectomy can be adversely affected by poor surgical results, the Executive Committee decided to establish a committee to set performance criteria and audit the surgical results of potential participants in ACAS. In this manner, it is anticipated that well-qualified surgeons competent to perform carotid endarterectomy will be selected as participants. Although it may be argued that this is

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an unrealistic representation of available surgical expertise in the country and that the results of carotid endarterectomy in specialized centers is not reflective of the overall surgical experience, both the Executive Committee and the Surgical Management Committee are convinced that participants with mediocre results would confound the outcome. It always could be argued that had we had "good" surgeons doing the operation the results may have been more favorable to surgery.

The objective of this report is to describe the methods used for auditing potential participants, to document the effect that this had on acceptance or rejection of surgeons and centers desirous of participating in the study, and to report the cumulative results of carotid endarterectomy among the audited surgeons who both passed the audit and failed the audit.

## Methods

As part of the initial review process to determine whether or not a clinical center is qualified to participate in ACAS, a review of all endarterectomies performed at the center's affiliated hospitals during the most recent 1-year period is required. A one-page data sheet is completed on each endarterectomy, which details basic patient history, the indication for the surgery, asymptomatic or symptomatic, amount of stenosis, and associated major and minor morbidity/mortality. Review of these preliminary data gives the Executive Committee an overall idea of complication rates and number of potential cases for the study.

Once a center was qualified to participate in the study, each potential participating ACAS surgeon was asked to submit the results of his or her last 50 consecutive carotid endarterectomies. The committee scrutinized the parameters of date of operation, indication for operation (asymptomatic, transient ischemic attack, prior stroke), duration of hospitalization, and outcome with regard to whether or not there was a postoperative death or stroke (30-day perioperative mortality/stroke morbidity). An on-site audit to verify the data was not performed.

The Surgical Management Committee expressed the opinion that both frequency of operation and outcome were important parameters in judging potential surgical participants. The committee decided that 12 carotid endarterectomies per year per surgeon was the minimum number acceptable. The committee decided that operations on asymptomatic patients must have a combined neurological morbidity and mortality rate of no greater than 3% and that the individual surgeon's results for the variety of indications for operation must not exceed a combined neurological morbidity and mortality rate of 5%.

Applicants whose results fell within the defined criteria were accepted as participating surgeons in ACAS. Those applicants whose results were clearly inferior to the defined criteria were rejected. In a few instances, in which applicants' experience was marginal, they were asked either to submit an additional 50 cases or to reapply when they could submit additional experience for committee judgment.

The Surgical Management Committee recognized that a sample of 50 cases may be insufficient to reflect the surgeon's true operative morbidity and mortality. For this reason, a continuing audit of performance was built into the study design. When an individual institution reports a postoperative complication of either death or stroke, that institution is put on a "watch" status by the Statistical Coordinating Center. If and when a second postoperative complication occurs at that institution, an institutional audit is triggered. This includes a re-review of both institutional and individual surgeons' results to determine whether or not an individual surgeon or institution should be suspended from the study because of unacceptably high complication rates related to operation.

The data accumulated from review of potential ACAS participants have been analyzed to document the total number of centers, the individual surgeons' results within each center, the number of surgeons approved for ACAS participation, documentation of the number of surgeons turned down for ACAS participation, and the effect that turndown had on whether or not a center could or could not participate in the study. Because each surgeon submitted experience with 50 operations, this gave us the opportunity to look at the total number of operations performed by surgeons who were both accepted and rejected. The operative mortality, the postoperative neurological morbidity, and the average hospital stay then could be determined. We further subdivided this assessment as a function of preoperative indication, looking at the total number of asymptomatic patients undergoing carotid endarterectomy, total number of patients undergoing carotid endarterectomy for transient ischemic attack, and total number of patients undergoing carotid endarterectomy with prior stroke as an indication for operation. Once again, the number of operations in each category, the operative morbidity, mortality, and average hospital stay were analyzed. Finally, the primary surgical specialty—vascular surgeon and neurological surgeon—was documented.

## Results

Forty-eight centers comprising one or more hospitals have completed the application process and have been reviewed as of February 1991. Thirty-eight centers have received approval and are active participants in ACAS. Seven centers have been rejected, and three centers remain in the pending category awaiting completion of their application material.

One hundred sixty-four surgeons have applied for ACAS approval and have submitted their operative experience. Of these, 141 are vascular surgeons, and 23 are neurosurgeons. One hundred seventeen applicants (71%) from 38 participating ACAS centers have been approved to participate in the study. One

**TABLE 1. Comparative Analysis of Morbidity and Mortality**

| Indication for operation | No. of operations (% total) | Mortality | Stroke | Average hospital stay (days) |
|---|---|---|---|---|
| Asymptomatic | 1,511 (26.8%) | 12 (0.8%) | 13 (0.9%) | 5.3 |
| Transient ischemic attack | 3,034 (53.8%) | 16 (0.5%) | 55 (1.8%) | 5.3 |
| Prior stroke | 1,096 (19.4%) | 17 (1.6%) | 21 (1.9%) | 6.3 |
| Overall | 5,641 (100%) | 45 (0.8%) | 87 (1.5%) | 5.5 |

hundred eight surgeons from 34 centers are currently randomizing cases. Ninety-eight of the 117 approved are vascular surgeons, and 19 are neurosurgeons. Seventeen surgeons (10%) were rejected as ACAS participants. The bases for rejection included fewer than 12 cases per year or an unacceptably high operative morbidity and mortality overall or in the category of operation on asymptomatic patients. Thirty surgeons were not reviewed either because of insufficient data or because their center was not approved.

Rejection of individual surgeons may have had no effect in the case of an individual center in which there were other approved surgeons, thus permitting the institution still to be an ACAS center. Other rejections have had a major effect, in that failure of one or more surgeons to qualify has led to the disqualification of the institution. Six of seven rejected institutions failed to qualify as an ACAS program because they were unable to provide a surgeon who met ACAS criteria.

A review of the surgical material provided by the ACAS applicants also permits an analysis of the operative morbidity, mortality, length of stay, and frequency in accumulating required cases. One hundred seventeen approved ACAS surgeons submitted a total of 5,641 carotid endarterectomies. These operations were performed over an average of 31 months, indicating that on the average, each surgeon performed approximately 20 carotid endarterectomies per year. Forty-five patients died within 30 days of operation or during the same hospitalization, for an operative mortality rate of 0.8%. Eighty-seven patients suffered a stroke ipsilateral to the side of operation within 30 days, for a perioperative neurological morbidity rate of 1.5%. This provides a combined mortality and neurological morbidity rate of 2.3% for the variety of indications for operation. The average length of hospital stay for each patient was 5.5 days.

Table 1 provides information on the indication for operation and compares this to the overall data. A total of 26.8% of operations were performed on asymptomatic patients with an operative mortality rate of 0.8%, a perioperative neurological complication rate of 0.9%, and an average hospital stay of 5.3 days. A total of 53.8% of operations were performed for the indication of transient cerebral ischemia. The overall mortality rate for that operative indication was 0.5%, and the perioperative neurological complication rate was 1.8%. The average hospital stay was 5.3 days. A total of 19.4% of patients were operated on for prior stroke in the distribution of the operated artery. The perioperative mortality rate was 1.6%, and the perioperative stroke rate was 1.9% with an average hospital stay of 6.3 days.

Table 2 compares the results between approved surgeons for ACAS and surgeons who were rejected as participants. The mortality rate for the unapproved surgeons was nearly three times greater than that for the approved group (2.25% versus 0.8%). The perioperative stroke rate was twice as high in the unapproved group as in the ACAS-approved group (3% versus 1.5%). The average hospital stay for patients operated on by unapproved surgeons was 6.5 days in comparison to 5.5 days for ACAS-approved surgeons.

## Discussion

The overall experience with carotid endarterectomy analyzed as a result of this auditing process is one of the largest series reported to date.[3] A total of 5,641 carotid endarterectomies performed by 117 ACAS-approved surgeons with an average 30-day mortality of 0.8% and perioperative stroke morbidity of 1.5% for a combined morbidity/mortality rate of 2.3% for the variety of indications for carotid endarterectomy is a remarkable achievement. This is well within the range of acceptable morbidity and mortality as recommended by the Stroke Council of the American Heart Association, even for their acceptable upper limit for asymptomatic carotid stenosis (<3%).[2] This is a particularly noteworthy accomplishment when one considers the fact that approximately three fourths of the operations reported were performed for the indication of transient ischemic attack or prior stroke, indications that the Stroke

**TABLE 2. Comparison of Overall Results Between Approved and Unapproved Surgeons**

| Category | No. of operations | Mortality | Stroke | Average hospital stay (days) |
|---|---|---|---|---|
| ACAS approved | 5,641 | 45 (0.8%) | 87 (1.5%) | 5.5 |
| ACAS unapproved | 976 | 22 (2.25%) | 29 (3%) | 6.5 |

ACAS, Asymptomatic Carotid Atherosclerosis Study.

Council has accepted as upper limits of combined morbidity and mortality of 5% and 7%, respectively.

It may be argued that the participating ACAS surgeons represent a unique group, the results from which will never be achieved by the community of surgeons at large. This is probably not the case because participating ACAS centers and surgeons represent a wide cross section of the practice community, including neurosurgeons and vascular surgeons, academic and community medical centers. Although the screening process used in ACAS is important in that it hopefully identified the best-qualified surgeons to participate, remarkably, only 10% of the applicants were turned down.

It may be argued that in the absence of an on-site audit, the surgeon's report of his own data may be suspect. Certainly, the potential for this exists, but several safeguards in the study were added to reduce this likelihood. First, an independent review of all carotid endarterectomies (independent of the individual surgeon's submission) was provided by the Principal Investigator of the proposed participating hospital. This gave the committee an overview of the entire experience of the hospital with which to compare the data subsequently submitted by the individual surgeon. If a discrepancy existed, this would have triggered further review. Second, most of the individual surgeons submitting their data also submitted patients' discharge summaries for committee review. Finally, the data requested for the individual patients required the surgeon to review the individual records and did not simply depend on the surgeon's recollection of results. Although an on-site audit of the results did not take place, it was clearly stated that the potential for this existed if a concern for the accuracy of the data was identified. Based on these cross checks of the data, the authors are convinced that the data are accurate.

The effectiveness of our screening program can only be judged on the completion of the study when the final data with respect to perioperative mortality and stroke morbidity will be available and can be compared with this retrospective analysis of audit data. However, several inferences can be made at this time. To date, only two centers have triggered a re-review because of two perioperative complications in each center. Each complication occurred in the hands of a different surgeon and, when evaluated in the overall context of the surgeons involved and the institution as a whole, was judged by the review team to be acceptable for the center to continue to randomize patients. These audits occurred early in the study, and neither of these institutions has experienced another complication. Of the 38 approved centers, 36 have not triggered an audit during the course of the study, indicating that these institutions have either had none or no more than one complication per institution for the course of the study to date. Although some institutions are new and have contributed only a few patients, most are well established with as many as 86 patients randomized from one center. Finally, the Data and Safety Management Committee, which oversees this study for the National Institutes of Health, was instructed to accept no more than a 3% combined operative mortality and perioperative stroke morbidity rate as set by the guidelines of the study and the guidelines of the Stroke Council of the American Heart Association. Should our complication rate exceed those guidelines, the study would be terminated. Although the actual results are not known to the authors, it would appear that among 733 patients randomized as of February 1991 (approximately one half the study requirement), the operative morbidity and stroke mortality is in compliance. Based on these inferences, it would appear that the selection process for surgeons to participate in ACAS has achieved its objective for safety and should serve as a model for selection of participants in future surgical studies.

## Appendix

Current participating centers and surgeons in the Asymptomatic Carotid Atherosclerosis Study:

*Arizona Health Sciences Center:* Victor Bernhard, Philip Carter, Glenn Hunter, and Kenneth McIntyre.

*University of Arkansas School of Medicine:* Robert Barnes and Bernhard Thompson.

*Barrow Neurological Institute:* Robert Spetzler and Joseph Zabramski.

*Bowman Gray School of Medicine:* Charles Branch, Robert Cordell, Richard Dean, J.M. McWhorter, and George Plonk.

*University of California, Los Angeles:* Samuel Ahn, J. Dennis Baker, Ronald Busuttil, Julie Freischlag, Herbert Machleder, Wesley Moore, and William Quiñones-Baldrich.

*University of California, San Diego:* Robert Hye, Marc Sedwitz, and Bruce Stabile.

*University of Cincinnati:* Richard Fowl, Richard Kempczinski, L. Richard Rodersheimer, John Tew, and Richard Welling.

*Columbia University:* James Correll and Donald Quest.

*Harbin Clinic:* John Kirkland, Leeon Rhoades, and Michael Rogers.

*Henry Ford Hospital:* Joseph Elliot, Calvin Ernst, Daniel Reddy, Alexander Shepard, and Roger Smith.

*Milton S. Hershey Medical Center:* Robert Atnip and Brian Thiele.

*Hôpital de L'Enfant Jesus:* Jean-Marie Bouchard, Jacques Cote, and Jean-François Turcotte.

*Francis Scott Key Medical Center:* Calvin Jones.

*University of Iowa Hospital & Clinics:* John Corson, John Godersky, Timothy Kresowik, Christopher Loftus, and Asad Shamma.

*University of Kentucky Medical Center:* Robert Dempsey, Eric Endean, and Byron Young.

*Lehigh Valley Hospital Center:* Victor Celani, James Goodreau, James McCullough, Kenneth McDonald, Gary Nicholas, and James Rex.

*Loyola University:* William Baker, Howard Greisler, and Fred Littooy.

*Marshfield Clinic:* R. Lee Kolts, M.D. Kuehner, and Mark Swanson.

*Medical College of Virginia:* H.M. Lee, Marc Posner, and Michael Sobel.

*University of Mississippi Medical School:* Robert Rhodes and Robert Smith.

*New England Medical Center:* William Mackey and Thomas O'Donnell.

*University of Medicine & Dentistry of New Jersey:* Robert Hobson and Zafar Jamil.

*University of New Mexico:* Eric Weinstein.

*Ochsner Clinic:* John Bowen, Larry Hollier, and John Ochsner.

*Oregon Health Sciences Center:* Gregory Moneta, John Porter, Lloyd Taylor, and Richard Yeager.

*Pacific Presbyterian Medical Center:* Robert Szarnicki and Charles Gould.

*St. John's Mercy Medical Center:* Arthur Auer, Joseph Hurley, Richard Pennell, and John Woods.

*Singing River Hospital:* Dewey Lane.

*Southwestern Medical Center:* Patrick Clagett.

*Sunnybrook Medical Center:* David Rowed.

*University of Tennessee:* Bijan Bakhtian, John Crockerall, James Robertson, and Clarence Watridge.

*University Hospital:* Gary G. Ferguson, S.J. Peerless, and Howard Reichman.

*Victoria Hospital:* Hugh Barr.

*Virginia Mason Research Center:* Edmond Raker and Terence Quigley.

*Yale University School of Medicine:* Douglas Chyatte, George Meirer, and Bauer Sumpio.

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