

A RAND NOTE

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THE APPROPRIATENESS OF CAROTID ENDARTERECTOMY

CONSTANCE M. WINSLOW, M.D., DAVID H. SOLOMON, M.D., MARK R. CHASSIN, M.D.,
JACQUELINE KOSECOFF, PH.D., NANCY J. MERRICK, M.D.,
AND ROBERT H. BROOK, M.D., Sc.D.

Abstract Carotid endarterectomy is a commonly performed but controversial procedure. We developed from the literature a list of 864 possible reasons for performing carotid endarterectomy, and asked a panel of nationally known experts to rate the appropriateness of each indication using a modified Delphi technique. On the basis of the panel's ratings, we determined the appropriateness of carotid endarterectomy in a random sample of 1302 Medicare patients in three geographic areas who had had the procedure in 1981.

Thirty-five percent of the patients in our sample had carotid endarterectomy for appropriate reasons, 32 percent for equivocal reasons, and 32 percent for inappropriate reasons. Of the patients having inappropriate surgery, 48 percent had less than 50 percent stenosis of the carotid artery that was operated on. Fifty-four percent of all the

procedures were performed in patients without transient ischemic attacks in the carotid distribution. Of these procedures, 18 percent were judged appropriate, as compared with 55 percent judged appropriate in patients with transient ischemic attacks in the carotid distribution. After carotid endarterectomy, 9.8 percent of patients had a major complication (stroke with residual deficit at the time of hospital discharge or death within 30 days of surgery).

We conclude that carotid endarterectomy was substantially overused in the three geographic areas we studied. Furthermore, in situations in which the complication rate is equal to or above the study's aggregate rate, carotid endarterectomy would not be warranted, even in cases with an appropriate indication, because the risks would almost certainly outweigh the benefits. (*N Engl J Med* 1988; 318:721-7.)

CAROTID endarterectomy is a commonly used procedure. From 1971 to 1982, the number of carotid endarterectomies performed yearly in the United States rose from 15,000 to 85,000.¹ An estimated 107,000 were performed in 1985.² However, there are substantial differences between geographic areas in the population-based rates at which this procedure is performed.³ Two randomized, controlled trials have compared the efficacy of carotid endarterectomy in preventing stroke or death with that of medical therapy or no therapy, but the results of the studies were equivocal.^{4,5}

Proponents of carotid endarterectomy maintain that if the operation had a low complication rate, it would be beneficial in certain clinical situations. Sev-

eral studies have described the circumstances under which carotid endarterectomy may be efficacious. The best available data suggest that the procedure may reduce the risk of stroke or death after an ipsilateral transient ischemic attack (TIA) in the carotid distribution in cases in which severe carotid artery stenosis is noted on angiography.⁴⁻⁷ The procedure is also performed in patients who have had a stroke⁸⁻¹⁰ or have a stroke in evolution¹¹ or in those who are asymptomatic but are at high risk for a stroke.^{12,13} In addition to our lack of data on the efficacy of carotid endarterectomy, we know little about how the procedure is actually being used throughout large geographic areas.

To learn more about the reasons for performing carotid endarterectomy, we investigated the appropriateness with which the procedure was performed in 1981 in patients receiving Medicare in three large geographic areas in the United States. We have recently reported the results of a study demonstrating the lack of a relation between the appropriateness and the rates of use of the procedure in these three areas.¹⁴ In all three sites a substantial proportion of use was inappropriate. We report here the clinical characteristics of the patients who underwent carotid endarterectomy, the importance of these clinical factors in deter-

From the Health Program of the Rand Corporation, Santa Monica, Calif.; the Departments of Medicine and Public Health of the University of California at Los Angeles; and Fink and Kosecoff, Inc., Santa Monica. Address reprint requests to Dr. Chassin at the Rand Corporation, 1700 Main St., P.O. Box 2138, Santa Monica, CA 90406-2138.

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mining appropriateness, and the perioperative complication rates in the three geographic sites studied.

METHODS

We used data from physicians' Medicare claims to measure population-based rates of use of carotid endarterectomy and other health services in 13 large geographic areas across the United States in 1981. The methods and results of this analysis have previously been reported.³ In 1981 the average rate of carotid endarterectomy among people 65 years of age or older in these 13 sites was 14 per 10,000 persons (adjusted for differences in age and sex). The rates observed ranged from a low of 6 to a high of 23 per 10,000; the differences were statistically significant ($P < 0.001$).

We selected three sites in which to study the appropriateness of carotid endarterectomy. We chose sites with rates at both extremes of the distribution, as well as a site with an average rate; thus, site 1 had a rate of 23 per 10,000, the highest rate we observed; site 3 had the lowest rate (6); and site 2 had a rate of 16. The sites are large geographic areas, together encompassing 1.5 million Medicare beneficiaries. Each site is the location of at least one medical school, with an overall total of eight. The sites also represent different degrees of urbanization; site 1 consists of a mixture of urban and rural areas, site 2 is relatively rural, and site 3 is more urban.

We have previously reported the methods we used to develop a catalogue of indications for carotid endarterectomy and to convene a panel of expert physicians to rate each indication on a scale of appropriateness.¹⁵⁻¹⁷ Briefly, we conducted an extensive literature review primarily to determine the circumstances under which carotid endarterectomy had been shown or thought to be beneficial. From this review we developed a list of 864 indications or specific clinical situations in which the use of this procedure might be considered. The list included essentially all possible reasons for performing the procedure.

We then convened a panel of nine nationally known experts in vascular surgery (three physicians), neurosurgery (one), neuroradiology (one), neurology (two), internal medicine (one), and family medicine (one). These physicians rated each indication on a 9-point scale of appropriateness (where 9 = extremely appropriate, 5 = equivocal, and 1 = extremely inappropriate). We considered a procedure appropriate if its expected health benefits exceeded its expected negative consequences by a margin wide enough to indicate that the procedure was worth doing. Panelists were provided with our literature review and asked specifically to rate the indications for carotid endarterectomy in 1981.

We used a modified Delphi technique in which panelists first rated the indications by mail, after which they met at Rand (in 1984), discussed their areas of disagreement, and rated the indications again. Consistent with the Delphi method, all individual ratings were kept confidential. To assist the panelists in the second round of ratings, each panelist received a summary of the group's ratings for each indication, displayed so that the panelist could compare his own rating with those of the rest of the group. The literature review and the list of 864 final rated indications are available elsewhere.¹⁵ We considered indications appropriate if the panel's median rating fell between 7 and 9 on our scale and the panel did not disagree. Inappropriate indications had median ratings of 1 to 3, without disagreement. We classified as equivocal all indications with median ratings of between 4 and 6 and all indications about which there was disagreement. For this purpose, we defined disagreement as occurring when at least three panelists rated the indication appropriate (7 to 9 on the scale) and at least three panelists rated the indication inappropriate (1 to 3).

The indications were structured to create homogeneous clinical groups. The 864 indications were organized according to 16 different clinical categories — 5 categories of carotid TIAs (Table 1), 2 categories including patients who had had strokes, 1 category each including patients with vertebrobasilar TIAs, stroke in evolution, and dementia, and 6 categories of asymptomatic patients. Patients were assigned to the TIA categories if their most recent TIA took place within three months of their surgery. Patients without symptoms were categorized according to whether they were to undergo

Table 1. Distribution of Patients with Carotid Endarterectomy, According to Clinical Group and Geographic Site.

CLINICAL GROUP	SITE 1	SITE 2	SITE 3
	(N = 600)	(N = 492)	(N = 210)
	% of patients at site		
Patients with carotid TIAs*	44	44	53
Single	12	16	15
Multiple in a patient not receiving medical therapy†	19	17	20
Multiple in a patient receiving medical therapy	8	8	13
Multiple in cases with treatment success‡	1	1	1
Crescendo	4	2	4
Asymptomatic patients§	28	25	23
Patients who had a stroke >3 wk before the procedure	16	17	11
Patients who had a stroke ≤3 wk before the procedure	5	5	5
Patients with verteobasilar TIAs	7	9	7
Patients with stroke in evolution	<1	0	1
Patients with dementia	<1	<1	<1

*The percentage of patients at site 3 with carotid TIAs was significantly different from the percentages at sites 1 and 2 ($P < 0.05$).

†Medical therapy was defined as any dosage of anticoagulant or platelet-inhibiting agent taken regularly.

‡Treatment success was defined as multiple TIAs within the previous year but no recurrence in the past three months in a patient receiving medical therapy.

§This category includes patients who had carotid endarterectomy before coronary-artery bypass surgery (3 percent) or intraabdominal or intrathoracic surgery (3 percent), as well as patients with nonspecific symptoms (9 percent) or asymptomatic carotid bruit (13 percent).

coronary-artery bypass surgery, intraabdominal or other intrathoracic surgery, or no surgery. Each of these categories was further subdivided into groups of patients with a normal or elevated risk of stroke. Patients with a high risk of stroke were identified with use of data from the Framingham study defining a probability of more than 10 percent that an atherothrombotic brain infarction would develop in eight years. The calculations of these probabilities take into account the patients' age, sex, smoking status, blood pressure, and serum cholesterol level as well as whether or not they had left ventricular hypertrophy and diabetes.¹⁵

Within each clinical category were three critical factors that defined the indications and therefore determined the appropriateness rating: the results of the carotid angiographic assessment, the estimated surgical risk, and when applicable, whether surgery was performed on the carotid artery ipsilateral or contralateral to the cerebral hemisphere associated with the patient's symptoms. The angiography results were classified according to the percentage reduction in the extracranial luminal diameter and the presence or absence of an ulcerative lesion. When the angiography report did not specify the exact percentage of stenosis, we assigned patients to the categories of stenosis as follows: "severe," "high-grade," and "tight" were included in the 70 to 99 percent category; "moderate" in the 50 to 69 percent category; and "mild," "minimal," and "normal" in the 0 to 49 percent category. The degree of intracranial stenosis was not included as a critical factor in defining indications. Ulcerative lesions were classified as small, large, or multicentric, according to the description in the angiography report. If the surgical team's interpretation of the angiography findings differed from that of the radiologist, we chose the reading that assigned patients to the category of greatest possible surgical benefit.

The patients were assigned to one of three categories of surgical risk with use of the Goldman index¹⁸ and the Dripps-American Society of Anesthesiology (ASA) criteria.¹⁹ Low risk was defined as Goldman Class I or Dripps-ASA Classes 1 and 2, medium risk as Goldman Classes II and III or Dripps-ASA Classes 3 and 4, and high risk as Goldman Class IV or Dripps-ASA Class 5. Patients in

the high-surgical-risk category had a more than 10 percent chance of having a major perioperative complication.

Using the claims data from which we calculated overall rates of use, we selected a random sample of 1589 cases in the three sites. We have described elsewhere the approach we used to obtain the participation of the community-based sample of physicians who performed the carotid endarterectomies.²⁰ The overall rate of physician participation was 89 percent (256 physicians). There were no significant differences between the sites in the rates of physician participation (91 percent at site 1, 85 percent at site 2, and 90 percent at site 3). Participating physicians had performed 89 percent ($n = 1414$) of the total number of procedures in the patient sample. The hospitals at which these procedures were performed also participated, except for one hospital in site 1 (whose physicians had agreed to participate). This hospital represented 3.2 percent ($n = 24$) of the patients selected for study in this site.

We requested the medical records of the 1390 cases in which the participating physicians and hospitals had been involved. A detailed abstraction form was developed to collect the data necessary to assign indications to each case. For example, we collected data on the presenting and previous neurologic symptoms (carotid TIAs, stroke, and vertebrobasilar TIAs), whether the patient was receiving medical therapy (anticoagulants or platelet-inhibiting drugs), the dates of any previous strokes, the patient's functional status at the time of admission and at discharge, previous carotid endarterectomies, risk factors for stroke (high cholesterol level, high blood pressure, smoking, and diabetes), surgical risk factors (comorbid conditions — e.g., a previous myocardial infarction), and noninvasive neurovascular studies and carotid angiograms. We defined a TIA in the carotid distribution as a transient unilateral neurologic deficit consistent with hemispheric ischemia and lasting less than 24 hours. We used Goldstone and Moore's definition of crescendo TIAs¹¹ — i.e., the occurrence of two or more carotid TIAs within a 24-hour period. We obtained photocopies of the results of all reports on carotid angiographic procedures and of most admission histories and physical examinations. The abstraction form and guidelines for its use are available elsewhere.¹⁵ We obtained data on deaths occurring within 30 days of the operation from the health insurance master file of the Health Care Financing Administration; this information is based on data pertaining to eligibility for Social Security. Information on operative complications (clinical details of any perioperative stroke or myocardial infarction) was also obtained from the medical records.

The medical records were abstracted by data collectors who were screened, trained, and monitored in order to ensure the collection of reliable and valid data. Each completed abstraction form was reviewed by both a physician and a nonphysician to assess the completeness and consistency of the clinical information. The physician also coded the results of all carotid angiograms from the carotid angiography reports and assigned cases to the clinical groups.

To obtain complete clinical data, the data collection took place in hospitals, physicians' offices, and clinics. Among the 1390 cases sampled from the claims data, we determined that there were errors in the claims data for 63 (4.5 percent): 40 of the procedures were not carotid endarterectomies, 7 were not performed in 1981, and 1 was not performed within the geographic area studied; for 15 procedures, the physician had no record of having seen the patient.

Data were incomplete in 25 cases (2 percent), which were excluded either because medical records known to exist could not be found (24 cases) or because available medical records from all sources did not provide enough data to allow us to determine the indication for the procedure (1 case). Thus, we were able to obtain complete information on 1302 cases, or 98 percent of all cases eligible for inclusion in the study after the claims errors were excluded.

On the basis of the data recorded in the abstraction forms, one or more indications were assigned to each case. In cases with more than one indication, the one with the highest appropriateness rating was designated the primary indication and was used throughout the subsequent analysis. We have previously reported studies of the validity of the complete process of medical-records abstraction, physician review, and assignment of indications.²⁰

Our calculations indicated that with 500 cases in each site, we could expect to detect a true difference of 8 percentage points in appropriate or inappropriate use in at least 80 percent of repeated trials. In sites 2 and 3, all Medicare patients who had a carotid endarterectomy in 1981 were selected for study. A random sample of patients, representing about half of all procedures, was selected for site 1.

Our sampling methods were designed so that all patients had an equal probability of being included. In order to obtain unbiased estimates, we used inverse sample-probability weighting to calculate the statistical values for all sites. We tested the differences between sites in the distributions of patients' characteristics and indications for carotid endarterectomy by using chi-square tests.

RESULTS

Table 2 shows the demographic and clinical characteristics of patients who underwent carotid endarterectomy in 1981 in the three geographic sites studied. The table also shows the sample size and the rate of carotid endarterectomy per 10,000 Medicare beneficiaries 65 years of age or older in each site. Except for age, there were no significant differences between the sites in any of the patients' characteristics. Site 3 had a smaller proportion of patients who were over 80 years old.

Table 1 lists the various clinical groups or presenting symptoms of the patients in the three sites. Slightly less than half the carotid endarterectomies in all three sites were performed in patients with carotid TIAs. Site 3 had a significantly higher proportion of patients who presented with carotid TIAs than did the other two sites (53 vs. 44 and 44 percent; $P < 0.05$). Patients who were asymptomatic or presented with nonspecific symptoms represented about one fourth of the entire sample of patients. Dementia and stroke in evolution were uncommon reasons for carotid endarterectomy.

Table 3 shows the appropriateness of carotid endarterectomy, according to site, and two important factors that, in addition to the clinical presentation, determine the appropriateness of carotid endarterectomy — stenosis of the carotid artery operated on and surgical risk. Overall, 32 percent of the carotid endar-

Table 2. Demographic and Clinical Characteristics of Patients Undergoing Carotid Endarterectomy in Three Geographic Sites in 1981.

	Site 1	Site 2	Site 3
No. of patients	600	492	210
Rate of carotid endarterectomy per 10,000 elderly persons	23	16	6
Age (%) ^a			
64-69	34	35	45
70-74	30	32	31
75-79	23	20	19
≥80	13	13	5
Sex (% male)	55	58	56
Race (% black)	1.2	0	4
Previous stroke (%)	30	29	27
Previous myocardial infarction (%)	25	26	20
Diabetes (%)	16	19	22

^a $P < 0.05$ for site 3 as compared with sites 1 and 2.

Table 3. Clinical Determinants of Appropriateness of Carotid Endarterectomy, According to Geographic Site.

	SITE 1 (N = 600)	SITE 2 (N = 492)	SITE 3 (N = 210)	ALL SITES (N = 1302)
	percent of patients*			
Appropriateness category†				
Appropriate	37	30	42	35
Equivocal	34	30	29	32
Inappropriate	30	40	29	32
% Stenosis in artery operated on‡				
0-49	17	24	20	19
50-69	18	17	17	17
70-99	64	56	61	62
Occluded	1	2	3	1
Surgical risk†				
Low	38	32	44	38
Medium	57	63	54	58
High	4	5	2	4

*Percentages may not sum to 100 because of rounding.

†P<0.05 for site 2 as compared with site 1 and for site 2 as compared with site 3.

‡P<0.05 for site 2 as compared with site 1.

terectomies were performed for inappropriate reasons. Site 2 had a significantly higher percentage of inappropriate procedures (40 percent) than did sites 1 and 3 (30 and 29 percent). A partial explanation for the higher percentage of inappropriate procedures in site 2 is that a higher percentage of patients had minimal (0 to 49 percent) carotid stenosis. For the most part, our panelists rated carotid endarterectomies as inappropriate when they were performed for indications associated with minimal stenosis of the artery. A few patients had carotid endarterectomies on an occluded vessel. The panel rated this indication as inappropriate regardless of the symptoms at presentation.

The majority of the patients were classified as having a medium surgical risk. Site 2 had the highest percentage of patients in this category. Surgery in this group, as compared with that in the low-risk group, was found, on the average, to be less appropriate, which contributed further to the higher percentage of inappropriate cases in site 2.

Tables 4 and 5 summarize the critical factors according to appropriateness category. Among all patients who presented with a carotid TIA (Table 4), carotid endarterectomy was judged appropriate in 55 percent. Eighty-three percent of the appropriate cases were in patients with low or medium surgical risk and severe (70 to 99 percent) stenosis of the carotid artery operated on. No carotid endarterectomies in patients with minimal stenosis and with no ulcer on carotid angiography were judged to be appropriate. Operations on patients at high surgical risk were rated as equivocal or inappropriate; they were never considered appropriate.

Twenty-eight percent of the carotid endarterectomies in patients who presented with carotid TIAs were inappropriate. Most of these patients (62 percent) had minimal carotid stenosis or complete occlusion of the artery (7 percent). In 10 percent of the inappropriate cases, the patients had a high degree of

stenosis of the artery operated on; however, this artery was contralateral to the involved hemisphere when the ipsilateral artery had severe stenosis.

Table 5 presents data on patients who did not present with carotid TIAs and were therefore considered to be less likely to benefit from surgery. A larger proportion of these patients than those with carotid TIAs were considered to have had inappropriate surgery (38 percent), and a smaller proportion were considered to have had appropriate surgery (18 percent). As compared with patients who presented with a TIA, a higher percentage of patients with either appropriate or equivocal procedures had severe (70 to 99 percent) stenosis of the carotid artery operated on. All patients at high surgical risk were considered to have had inappropriate surgery.

Table 6 shows the rate of major complications in each site. Operative mortality, defined as death occurring within 30 days of surgery, was 3.4 percent, representing 44 deaths in the entire sample. Perioperative stroke, defined as a new stroke occurring during or after surgery and causing a residual (still present on hospital discharge) neurologic deficit that impaired function in a patient who did not die within 30 days after surgery, occurred in 6.4 percent of all patients. There were differences between the sites, but they did not reach statistical significance (P>0.05). The rate of major operative complications (stroke with residual deficit or 30-day mortality) in all three sites combined was 9.8 percent. Postoperative nonfatal myocardial infarctions in patients who did not have a stroke occurred in 1.8 percent of cases in the entire sample.

Whether an operation was appropriate did not affect the complication rate, although there tended to be more complications in patients who had inappropriate operations. The rates of major complications were 8.3 percent for the appropriate procedures, 10.0 percent for the equivocal procedures, and 10.8 percent for the

Table 4. Characteristics of 593 Patients Who Presented with Carotid Transient Ischemic Attacks.

	APPROPRIATENESS CATEGORY		
	APPROPRIATE (N = 328)	EQUIVOCAL (N = 99)	INAPPROPRIATE (N = 166)
	percent of patients*		
Patients with low or medium surgical risk†			
0-49%			
Without ulcer	0	15	45
With ulcer	4	7	17
50-69%			
Without ulcer	10	17	10
With ulcer	3	10	5
70-99%	83	44	10
Occluded artery	0	0	7
Patients with high surgical risk	0	6	7
All patients presenting with carotid TIAs	55	17	28

*Percentages may not sum to 100 because of rounding.

†Percentages are the reductions reported on carotid angiography in the luminal diameter of the artery operated on. "Ulcer" was defined to include possible as well as definite ulcers.

inappropriate procedures. The differences between these rates were not statistically significant.

DISCUSSION

We studied the appropriateness of the use of carotid endarterectomy in 1981 in the elderly Medicare population in three large geographic areas. The sites were selected because they represented a spectrum of rates at which the procedure was used. Previously, we reported that the 3.8-fold difference in the population-based rates of use between the sites of high and low use was not explained by differences in appropriateness.¹⁴ Approximately one third of the procedures in the three sites were considered inappropriate. Four factors accounted for three fourths of all inappropriate procedures: operations on arteries with minimal stenosis (48 percent), operations on patients at high surgical risk (11 percent), operations on arteries contralateral to the hemisphere associated with the symptoms when the ipsilateral artery had severe stenosis (9 percent), and operations on completely occluded vessels (6 percent). These data suggest that there is substantial overuse of carotid endarterectomy in the three geographic areas studied.

The goal of a carotid endarterectomy is to reduce the risk of stroke in patients with extracranial vascular disease. For the procedure to be effective, the risk of stroke should be lower after surgery than before surgery. Patients who would be most likely to benefit from the procedure are those with carotid TIAs in whom severe carotid-artery stenosis is present on angiography.^{4,7} Several studies of the natural history of untreated TIAs suggest that such patients have an annual risk of stroke of about 10 percent.^{21-23a} Less is known about the natural history of cerebrovascular disease in patients with asymptomatic carotid-artery disease.²⁴⁻³⁰ The wide range of annual rates of stroke and mortality in these patients may reflect the heterogeneity of the populations studied. The incidence of stroke or death increases progressively with the sever-

Table 5. Characteristics of 709 Patients Who Did Not Present with Carotid Transient Ischemic Attacks.

	APPROPRIATENESS CATEGORY		
	APPROPRIATE (N = 127)	EQUIVOCAL (N = 313)	INAPPROPRIATE (N = 269)
	<i>percent of patients</i>		
Patients with low or medium surgical risk*			
0-49%			
Without ulcer	0	0	24
With ulcer	3	1	15
50-69%			
Without ulcer	4	4	21
With ulcer	2	8	12
70-99%	91	87	9
Occluded	0	0	5
Patients with high surgical risk	0	0	14
All patients not presenting with carotid TIAs	18	44	38

*Percentages are the reductions reported on carotid angiography in the luminal diameter of the artery operated on. "Ulcer" was defined to include possible as well as definite ulcers.

Table 6. Major Complications of Carotid Endarterectomy, According to Geographic Site.

	SITE 1 (N = 600)	SITE 2 (N = 492)	SITE 3 (N = 210)	ALL SITES (N = 1302)
	<i>percent of patients*</i>			
Thirty-day mortality	3.6	2.6	4.3	3.4
Stroke with residual deficit on discharge	5.8	6.9	8.1	6.4
Total with major complications†	9.4	9.6	12.4	9.8
Nonfatal myocardial infarction	2.0	1.4	1.4	1.8

*Percentages may not sum to 100 because of rounding.

†None of the differences between the sites were statistically significant (P>0.05).

ity of carotid-artery stenosis, but the estimated average risk of stroke is 3 percent per year. Even this estimate may be too high for assessing the possible benefit of carotid endarterectomy, however, because several of the studies of the natural history of strokes have reported the rates of all strokes, including those involving the hemisphere contralateral to the stenosis, those occurring in the vertebrobasilar circulation, and those that are probably caused by cardiac emboli.^{28,30} In addition, in estimating the current risk of stroke in asymptomatic patients, these investigations did not take into account the well-documented declining incidence of stroke.³¹

The rate of major complications in our sample was 9.8 percent. There were no statistically significant differences between the sites studied. The rate of serious perioperative complications from carotid endarterectomy has been found to range from 0 to 21 percent,^{7,13,32-41} with the majority of the complication rates under 4 percent observed in academic medical centers. Rates of 9 to 10 percent have been reported in some community practices.^{39,40} Researchers have suggested that rates of 3 to 4 percent would result in a net reduction in the incidence of stroke over a five-year period.^{13,32} The panel in our study thought that if the rate of major complications among an individual surgeon's patients was above 8 percent, it would be inappropriate for that surgeon to perform carotid endarterectomy under any circumstances.⁴² Since our sample sizes were too small to allow us to estimate physician-specific complication rates precisely, the rate of 9.8 percent we report here is an aggregate one. However, our data suggest that the complication rates among the patients of most individual physicians exceeded 3 to 4 percent, implying that because we did not adjust for the physician-specific rates of complications in our definition of appropriateness, we underestimated the rate of inappropriate use of carotid endarterectomy. If a surgeon's patients have a complication rate of 10 percent (the average in our study), the efficacy and appropriateness of that surgeon's performing carotid endarterectomy in any group of patients are questionable.

Two factors may limit the generalizability of our findings. First, we studied carotid endarterectomies performed in 1981, and our panel rated the appropriateness of the procedures on the basis of information

that was available in 1981. Advances in medical practice have occurred since that time, and the perioperative mortality and morbidity rates may have improved. Brott et al.³⁹ have reported that the rates of perioperative stroke and operative mortality decreased from 1980 to 1984 in their series of patients. The population they studied was similar to ours in that 50 percent of the patients had the procedure because of asymptomatic carotid disease. Their combined rate of stroke or death in 1984 (6.5 percent), however, was still well above that acceptable for prophylactic surgery in asymptomatic patients. In addition, Dyken has documented an inpatient mortality rate of 3.3 percent among patients undergoing carotid endarterectomy in Indiana between 1984 and 1986.⁴³ This figure is higher than the inpatient mortality rate in our study (3.0 percent).

Improved techniques for diagnosing carotid artery disease, such as digital subtraction angiography, were not commonly available in 1981 but are widely used today. Noninvasive techniques such as periorbital directional Doppler ultrasonography, ophthalmodynamometry, and oculoplethysmography now allow better definition of disease processes. These improved diagnostic techniques would not, however, be expected to affect the appropriateness of carotid endarterectomy.

The second factor that may limit the generalizability of our results is that we studied elderly patients. We do not know whether carotid endarterectomies are used more appropriately in younger persons, but most of these procedures are performed in people who are 65 years old or older; in 1985, of the 107,000 carotid endarterectomies performed in the United States, 70 percent were performed in patients in that age group.²

Our standards for determining the appropriate use of carotid endarterectomy reflect the mainstream of medical opinion. The reliability and validity of our ratings have been described, and they are consistent with the literature on carotid endarterectomy.⁴⁴ Our panel was selected to represent various specialties and practices. Although the ratings may reflect the composition of that panel, most physicians would agree, for example, that carotid endarterectomy is inappropriate in asymptomatic patients who also have either minimal carotid stenosis or complete occlusion of the carotid artery operated on.

In summary, our findings show that 32 percent of the carotid endarterectomies we evaluated were performed for inappropriate reasons. Fifty-four percent of the procedures were performed in patients without carotid TIAs, and 19 percent in patients with minimal (0 to 49 percent) stenosis of the artery operated on. Moreover, because of the high rate of complications, carotid endarterectomy may not benefit even patients who are operated on for appropriate indications. The Committee on Health Care Issues of the American Neurological Association recently concluded that in patients with TIAs, "carotid endarterectomy may be of value, provided the procedures are performed with a very low surgical complication rate."^{23a} We believe

that our findings raise important questions about the use of carotid endarterectomy in elderly patients. In the absence of solid clinical evidence that this procedure reduces the risk of stroke, and because of the high rate of complications we observed, the use of this procedure should be curtailed and perhaps limited to surgeons and hospitals performing few inappropriate procedures, with acceptable rates of complications. Physicians should review both the reasons carotid endarterectomy is performed and the current level of complications associated with the procedure in their own institutions.

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REFERENCES

1. Dyken ML, Pokras R. The performance of endarterectomy for disease of the extracranial arteries of the head. *Stroke* 1984; 15:948-50.
2. National Center for Health Statistics, Pokras R. Detailed diagnoses and procedures for patients discharged from short-stay hospitals: United States, 1985. Vital and health statistics. Series 13, No. 90. Washington, D.C.: Government Printing Office, 1987. (DHHS publication no. (PHS) 87-1751.)
3. Chassin MR, Brook RH, Park RE, et al. Variations in the use of medical and surgical services by the Medicare population. *N Engl J Med* 1986; 314:285-90.
4. Fields WS, Mastenikov V, Meyer JS, Hass WK, Remington RD, MacDonald M. Joint study of extracranial arterial occlusion. V. Progress report of prognosis following surgery or nonsurgical treatment for transient cerebral ischemic attacks and cervical carotid artery lesions. *JAMA* 1970; 211:1993-2003.
5. Shaw DA, Venables GS, Cartledge NEF, Bates D, Dickinson PH. Carotid endarterectomy in patients with transient cerebral ischaemia. *J Neurol Sci* 1984; 64:45-53.
6. Byer JA, Easton JD. Transient cerebral ischemia: review of surgical results. *Prog Cardiovasc Dis* 1980; 22:389-96.
7. Whisnant JP, Sandok BA, Sundt TM. Carotid endarterectomy for unilateral carotid system transient cerebral ischemia. *Mayo Clin Proc* 1983; 58:171-5.
8. Takolander RJ, Bergentz S-E, Ericsson BF. Carotid artery surgery in patients with minor stroke. *Br J Surg* 1983; 70:13-6.
9. Allen GS, Preziosi TJ. Carotid endarterectomy: a prospective study of its efficacy and safety. *Medicine* 1981; 60:298-309.
10. Whittemore AD, Ruby ST, Couch NP, Mannick JA. Early carotid endarterectomy in patients with small, fixed neurologic deficits. *J Vasc Surg* 1984; 1:795-8.
11. Goldstone J, Moore WS. A new look at emergency carotid artery operations for the treatment of cerebrovascular insufficiency. *Stroke* 1978; 9:599-602.
12. Quiñones-Baldrich WJ, Moore WS. Asymptomatic carotid stenosis: rationale for management. *Arch Neurol* 1985; 42:378-82.
13. Chambers BR, Norris JW. The case against surgery for asymptomatic carotid stenosis. *Stroke* 1984; 15:964-7.
14. Chassin MR, Kosecoff J, Park RE, et al. Does inappropriate use explain geographic variations in the use of health care services? A study of three procedures. *JAMA* 1987; 258:2533-7.
15. Merrick NJ, Park RE, Kosecoff J, et al. A review of the literature and ratings for the appropriateness of indications for selected medical and surgical procedures: carotid endarterectomy. Santa Monica, Calif.: Rand Corporation, 1986. (Publication no. R-3204/6.)
16. Park RE, Fink A, Brook RH, et al. Physician ratings of appropriate indications for six medical and surgical procedures. *Am J Public Health* 1986; 76:766-72.
17. Park RE, Fink A, Brook RH, et al. Physician ratings of appropriate indications for six medical and surgical procedures. Santa Monica, Calif.: Rand Corporation, 1986. (Publication no. R-3280.)
18. Goldman L, Caldera DL, Nussbaum SR, et al. Multifactorial index of cardiac risk in noncardiac surgical procedures. *N Engl J Med* 1977; 297:845-50.

19. Dripps RD, Lamont A, Eckenhoff JE. The role of anesthesia in surgical mortality. *JAMA* 1961; 178:261-6.
20. Kosecoff J, Chassin MR, Fink A, et al. Obtaining clinical data on the appropriateness of medical care in community practice. *JAMA* 1987; 258:2538-42.
21. The Canadian Cooperative Study Group. A randomized trial of aspirin and sulfipyrazone in threatened stroke. *N Engl J Med* 1978; 299:53-9.
22. Baker RN, Ramseyer JC, Schwartz WS. Prognosis in patients with transient cerebral ischemic attacks. *Neurology* 1968; 18:1157-65.
23. Whisnant JP, Matsumoto N, Elveback LR. Transient cerebral ischemic attacks in the community: Rochester, Minnesota, 1955 through 1969. *Mayo Clin Proc* 1973; 48:194-8.
- 23a. Committee on Health Care Issues, American Neurological Association. Does carotid endarterectomy decrease stroke and death in patients with transient ischemic attacks? *Ann Neurol* 1987; 22:72-6.
24. Thompson JE, Patman RD, Talkington CM. Asymptomatic carotid bruit: long-term outcome of patients having endarterectomy compared with unoperated controls. *Ann Surg* 1978; 188:308-16.
25. Dorazio RA, Ezzet F, Nesbitt NJ. Long-term follow-up of asymptomatic carotid bruits. *Am J Surg* 1980; 140:212-3.
26. Grotta J, Fields WS, Kwee K. Prognosis in patients with asymptomatic carotid bruits due to nonstenotic lesions. *Ann Neurol* 1982; 12:85. abstract.
27. Javid H, Ostermiller WE, Hengesh JW, et al. Carotid endarterectomy for asymptomatic patients. *Arch Surg* 1971; 102:389-91.
28. Chambers BR, Norris JW. Outcome in patients with asymptomatic neck bruits. *N Engl J Med* 1986; 315:860-5.
29. Heyman A, Wilkinson WE, Heyden S, et al. Risk of stroke in asymptomatic persons with cervical arterial bruits: a population study in Evans County, Georgia. *N Engl J Med* 1980; 302:838-41.
30. Wolf PA, Kannel WB, Sortie P, McNamara P. Asymptomatic carotid bruit and risk of stroke: the Framingham study. *JAMA* 1981; 245:1442-5.
31. Whisnant JP. The decline of stroke. *Stroke* 1984; 15:160-8.
32. Warlow C. Carotid endarterectomy: Does it work? *Stroke* 1984; 15:1068-76.
33. Easton JD, Sherman DG. Stroke and mortality rate in carotid endarterectomy: 228 consecutive operations. *Stroke* 1977; 8:565-8.
34. Kistler JP, Ropper AH, Heros RC. Therapy of ischemic cerebral vascular disease due to atherothrombosis. *N Engl J Med* 1984; 311:100-5.
35. Ennix CL Jr, Lawrie GM, Morris GC Jr, et al. Improved results of carotid endarterectomy in patients with symptomatic coronary disease: an analysis of 1,546 consecutive carotid operations. *Stroke* 1979; 10:122-5.
36. Bernstein EF, Humber PB, Collins GM, Dilley RB, Devin JB, Stuart SH. Life expectancy and late stroke following carotid endarterectomy. *Ann Surg* 1983; 198:80-6.
37. Nunn DB. Carotid endarterectomy: an analysis of 234 operative cases. *Ann Surg* 1975; 182:733-8.
38. Toole JF, Yuson CP, Janeway R, et al. Transient ischemic attacks: a prospective study of 225 patients. *Neurology* 1978; 28:746-53.
39. Brott TG, Labutta RJ, Kempczinski RF. Changing patterns in the practice of carotid endarterectomy in a large metropolitan area. *JAMA* 1986; 225:2609-12.
40. Modi JR, Finch WT, Summers DS. Update of carotid endarterectomy in two community hospitals: Springfield revisited. *Stroke* 1983; 14:128. abstract.
41. Fode NC, Sundt TM Jr, Robertson JT, Peerless SJ, Shields CB. Multicenter retrospective review of results and complications of carotid endarterectomy in 1981. *Stroke* 1986; 17:370-6.
42. Merrick NJ, Brook RH, Fink A, Solomon DH. Use of carotid endarterectomy in five California Veterans Administration medical centers. *JAMA* 1986; 256:2531-5.
43. Dyken ML. Carotid endarterectomy studies: a glimmering of science. *Stroke* 1986; 17:355-8.
44. Merrick NJ, Fink A, Park RE, et al. Derivation of clinical indications for carotid endarterectomy by an expert panel. *Am J Public Health* 1987; 77:187-90.

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