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Carotid Endarterectomy Among Medicare Beneficiaries

A Statewide Evaluation of Appropriateness and Outcome

Herbert R. Karp, MD; W. Dana Flanders, MD, DSc; Clanton C. Shipp, MPA, MSOR; Brenda Taylor, BSN, MHA; Debra Martin, RN

Background and Purpose**—**We sought to examine the appropriateness and the surgical outcomes of carotid endarterectomy (CE) in unselected community hospitals to identify opportunities for improvement.

Methods**—**We performed a retrospective review of all CEs performed on Medicare beneficiaries in Georgia in 1993 (n=1945). Conclusions regarding appropriateness were based on current guidelines as interpreted by a physician reviewer and were supported by the aggregate results of structured, blinded overreading by clinicians with relevant expertise. Adverse outcomes were confirmed and rated as to severity by a physician. Outcomes were correlated with demography, vascular anatomic findings, comorbidity, surgical techniques, and hospital characteristics.

Results**—**The majority of the patients (51%) were asymptomatic at presentation. CEs were performed appropriately in 96.1% of the cases in accordance with current guidelines. There was no significant difference in the rate of appropriateness between the symptomatic (96%) and the asymptomatic patients (96.4%). Survival without stroke or myocardial infarction (MI) was 94.3%. The 30-day mortality was 1.9%; moderate to severe strokes occurred in 1.8%, stroke-related death in 0.7%, MI in 1.1%, and MI-related death in 0.5%. Those hospitals performing <10 CEs in the observed year had a statistically significant higher morbidity and mortality as well as an increase in less severe complications such as hematomas, wound dehiscence, wound infection, and pneumonia than did hospitals with higher volume of CEs.. Older patients and women had statistically significantly higher morbidity and mortality. Patients with a Charlson Severity Index score of ≥1 had a risk for adverse outcomes 3.4 times higher than patients with a score of 0 after adjustment for age and sex.

Conclusions**—**The great majority of CEs performed in Georgia on Medicare patients were appropriate, according to current guidelines. Slightly more than half of the patients were asymptomatic as defined in the Asymptomatic Carotid Atherosclerosis Study. In hospitals performing <CEs in the index year, we noted higher morbidity and mortality, as well as an increase in less severe complications. This relationship between the volume of surgery and outcome was confirmed in the analysis of the 30-day mortality for all Medicare cases (n=10 569) performed in Georgia from 1991 to 1995. This was the most important opportunity for improvement identified in this study. In view of the increased use of CE, it is important to continue to monitor the patterns of practice for this procedure to improve outcomes. **(*Stroke.* 1998;29:46-52.)**

Key Words: appropriateness review ■ carotid artery disease ■ community hospitals ■ endarterectomy ■ outcome ■ physicians' practice patterns ■ retrospective chart review ■ utilization review

Clinical trials have demonstrated that CE, when used appropriately and performed with acceptable postsurgical morbidity and mortality, is effective in preventing cerebral infarction.[1–3] The patients in these studies were carefully selected, and participating surgeons and institutions were thoroughly evaluated for low morbidity and mortality before participating in the trials.[4] None of these studies represented the total experience of CE at a given institution, nor were they a valid representation of the patterns of practice in the general community.

The combined mortality and morbidity after CE in the United States has been estimated to be between 6% and 10%.[5] In a study of 1160 patients randomly selected from all patients undergoing CE in 12 university hospitals from 1988 to 1990, McCrory et al[6] reported that 6.9% had either a nonfatal stroke, nonfatal MI, or death. The overall mortality rate was 1.4%. In

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Selected Abbreviations and Acronyms

ACAS	= Asymptomatic Carotid Atherosclerosis Study
CABG	= coronary artery bypass graft
CE	= carotid endarterectomy
MI	= myocardial infarction
TIA	= transient ischemic attack

addition, 3.4% had a nonfatal stroke and 2.1% a nonfatal myocardial infarction, resulting in a combined morbidity mortality rate of 6.9%. In contrast, studies from nonuniversity, community hospitals have reported mortality rates in the range of 3% and combined morbidity and mortality rates varying from 6% to 20%.[7–10] In a more recent study, Yates et al[11] reported combined stroke mortality rates of 2.1% and 2.3% for patients treated by academic and community surgeons, respectively.

In a study of the appropriateness of CE, using a modified Delphi technique, Winslow et al[12] studied the appropriateness of CE and reported that 35% of a random sample of 1302 Medicare patients had appropriate reasons for undergoing this surgical procedure, 32% had equivocal reasons, and 32% had inappropriate reasons.

The purpose of this study was to examine the appropriateness and the surgical outcomes of CE for all Medicare beneficiaries in a single state to identify opportunities for improvement.

Methods

We selected for study all 1993 Medicare admissions in Georgia with a procedure code for CE (*International Classification of Diseases, 9th Revision, Clinical Modification* code 38.12) (n=1980). We excluded 35 cases because of incomplete medical record data or inaccurate procedure code billing information. Trained medical record abstractors reviewed and abstracted the remaining 1945 cases using a computerized data entry system. The reliability of the data abstraction was enhanced by structured overreading as described below.

We abstracted the following data: (1) clinical classification (ie, signs and symptoms for which a CE might be considered); (2) findings on arterial imaging; (3) clinical risk factors; and (4) characteristics of the surgical procedure and the hospital. Hospitals were grouped according to the volume of CEs performed on Medicare beneficiaries in the year of the study: 1 to 10, 11 to 25, 26 to 50, and 51 to 250.

Before the medical records were abstracted, the results of carotid imaging studies were reviewed. If this information was absent, then the collaborating hospitals were asked to provide such records. If the preferred imaging procedure, arteriography, was not available, then we abstracted the results of noninvasive imaging. We abstracted the report of the radiologist or vascular laboratory or, if this was not available, the report of an attending physician. We used numerical descriptors of the degree of stenosis when present in the record; if these were absent, we converted narrative descriptors to numerical values: normal=0%; mild=35%; moderate=60%; marked=75%; subtotal=95%; total=100%. Although somewhat arbitrary, this grouping of the degrees of stenosis corresponded to those that are used clinically. The presence of tandem lesions was noted. Because of inherent limitations in the reliability of the characterization of plaques and ulcers, these lesions were listed as either large or small. To define asymptomatic patients in this study, we used the definition of the ACAS,[3] ie, the absence of symptoms in the distribution of the operated artery.

Appropriate Clinical Indications for CE

To define strata for sampling, we used a computer algorithm developed by the Georgia Medical Care Foundation and Case Mix Research, Queen's University, Ontario, Canada. This algorithm was based on an instrument initially developed by an expert consensus panel convened by the RAND Corporation and the Academic Medical Center Consortium.[13] The algorithm also incorporated the practice guidelines promulgated by an ad hoc committee of the Joint Council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery.[14]

The algorithm served to separate patients into two groups: those in whom the CE was "likely" to be appropriate and those in whom the CE was "possibly" inappropriate. The primary reviewer, H.R.K., reviewed a 100% sample of the charts in the "possibly inappropriate" group (n=290) and a random sample of charts from the "likely appropriate" group (n=58). The primary reviewer was blinded as to the data entered by the abstractor and the classification assigned by the algorithm.

The appropriateness rate for CE was based entirely on extrapolating the results of the assessment in these two samples by the primary reviewer. His assessment was based on the current indications for CE as defined by an ad hoc multidisciplinary committee of the American Heart Association.[15] The indications assigned to an asymptomatic patient with a surgical risk of <3% and symptomatic patients with a surgical risk of <6% were the basis for the determination. A case was characterized as appropriate if it satisfied the committee's "proven" or "acceptable but not proven" indications for CE, and it was characterized as inappropriate if the data indicated that the case was in the category of "uncertain" or "proven inappropriate" (Appendix). We emphasize that the computer algorithm served only to define the strata for sampling.

To assess validity, each chart in a randomly selected sample of 50 charts was rated for appropriateness by the primary reviewer. In addition, five panels consisting of a surgeon and a nonsurgeon each blindly reviewed a different subset of the 50 charts rated by the primary reviewer. The ad hoc panel was instructed to base their decisions on their clinical experience and best judgment as well as the current guidelines. The primary reviewer used the current guidelines as noted above.

In this small sample, the agreement between the primary reviewer and the nonsurgeon physicians was slight (κ=.2; 95% confidence interval, 0.1 to 0.5). The agreement between the primary reviewer and the surgeon reviewers was good (κ=.7; 95% confidence interval, 0.1 to 0.9). Nevertheless, the primary reviewer agreed with the nonsurgeons in 88% of the cases and with the surgeons in 98%.

Postoperative Morbidity and Mortality

Satisfactory outcome was defined as 30-day survival free of hospitalization-associated stroke or MI. Postdischarge status was determined by readmission to any hospital for stroke or MI within 30 days of the surgery. Deaths were identified from Medicare claim files or from Social Security files if the patient died at home. A stroke was defined as a focal neurological deficit in the vascular territory of the operated or other arteries that persisted for more than 24 hours. The definition was not dependent on documentation by CT or MRI. A stroke was classified as (1) minor if the resulting deficit was not disabling and the patient was able to perform most activities of daily living and could walk without assistance, (2) moderate if the patient was able to perform most activities of daily living but required assistance in walking, and (3) severe if the patient required assistance in performing the usual activities of daily living or was in a persistent vegetative state.[16] A physician reviewed all records in which the abstractor had determined that the patient had a stroke in the perioperative period to verify that the patient had a stroke and to determine the severity of the deficit.

Statistical Analysis

We used *t* tests and χ^2 tests of association. When cell sizes were small, we used Fisher's exact test and associated confidence limits. We used multiple logistic regression to assess the association of mortality with potential risk factors and to evaluate potential confounding. Potential risk factors included the Charlson Index as well as demographic and anatomic characteristics of patients, such as age and degree of stenosis. On the basis of other analyses comparing the Charlson

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TABLE 1. Number of Cases by Clinical Classification

Clinical Classification	No.	%
Stroke in evolution	9	0.5
Mild/moderate stroke <3 wk	83	4.3
Mild/moderate stroke >3 wk	148	7.6
Multiple TIAs	17	0.9
Single TIA	686	35.3
Asymptomatic	1002	51.5

Index (resulting from chart abstraction) with an index based on billing data (S.M. Kieszak et al, unpublished data, 1996), we created dichotomous indices by grouping patients with a weighted comorbidity score of 0 and a weighted comorbidity score ≥1, as suggested by Charlson et al.[17] The relation of surgical techniques (eg, the use of patches and shunts) and the type of anesthesia were also assessed. Hospital characteristics included the number of CEs performed on Medicare beneficiaries by each hospital in the study year. To study these risk factors further, we used mortality as well as moderate or severe stroke rather than just mortality as the outcome. We assessed dose response for ordinal risk factors by assigning a score of 0 to the lowest category, 1 to the next higher, and so forth. The scored variable was entered as a continuous variable in the logistic regression model. Since the frequency of severe stroke or death is relatively uncommon, odds ratios can be interpreted approximately as risk ratios.[18]

Results

The mean age of eligible patients undergoing CE (n=1945) was 72.3 years; 53.2% were male, 46.8% female.

Approximately 4.8% of the patients were black, 90.5% were white, and 4.7% were other or unknown. The racial distribution of patients differed from that of all Medicare beneficiaries, approximately 22% of whom were black and 76% white.

Approximately one half (51%) of the patients were asymptomatic at presentation; approximately one third had a single TIA. The remainder had either multiple TIAs, mild stroke, or a stroke in evolution (Table 1). At admission, many patients had peripheral vascular disease, history of MI, diabetes, or other associated illnesses, as shown in Table 2. Plaque was noted in 50.3% of cases, almost half of which were described as large. Ulceration of the plaque was described in 22.9%.

Appropriateness of Carotid Surgery and Postoperative Outcome

Based on the current guidelines as defined by the American Heart Association ad hoc panel and as reviewed by us, CE was performed appropriately in an estimated 96% of the 1945 patients. There was no significant difference in the rate of appropriateness between the symptomatic (96%) and the asymptomatic patients (96.4%). Moreover, in the validity sample referred to in "Methods," the nonsurgeons and surgeon reviewers, respectively, rated 90% and 92% of the 50 cases as appropriate, similar to the 94% rated as appropriate by the primary reviewer for this sample.

TABLE 2. Predominant Comorbidities

Comorbidity	No.	%
Peripheral vascular disease	567	29.2
Chronic pulmonary disease	467	24
Previous MI	448	23
Diabetes	388	19.9
Peptic ulcer disease	201	10.3
Any malignancy	179	9.2
Congestive heart failure	145	7.5
Dementia	47	2.4
Diabetes with chronic complications	32	1.6
Renal disease	29	1.5

The mortality within the 30-day period was 1.9% (n=36). Only six deaths occurred after discharge. The frequencies of readmission for stroke and MI within this period were 0.6% and 0.3%, respectively. The overall survival without stroke or MI was 94.3%. The relationships of morbidity and mortality to clinical classification are summarized in Table 3.

Tables 4 and 5 summarize the relation of severe stroke or death within 30 days of surgery to demographic characteristics, Charlson Severity Index, hospital characteristics, appropriateness, vascular and surgical factors, and type of anesthesia. Older patients and women had increased postoperative morbidity and mortality. Patients who had a Charlson score ≥1 had a risk of morbidity and mortality that was 3.4 times higher, after adjustment for age and sex, than that of patients with a Charlson score of 0 (P=.005).

Occlusion of the nonoperated carotid artery was not associated with increased risk of adverse outcome. However, several vascular anatomic characteristics were associated with risk for stroke or death (eg, >95% stenosis, plaques, and ulcers). The associations for most of these characteristics lacked statistical significance, and confidence limits were wide, reflecting the low frequency of adverse events. Shunts were used in >50% of the cases, suggesting that shunts were used routinely in many instances. The finding of a higher incidence of stroke associated with the use of shunts may reflect the fact that those patients were clinically less stable. However, an alternative explanation is that the routine use of shunts may be a risk factor.

Patient mortality and severe stroke increased as the volume of CEs performed at each hospital decreased.(Table 4) The mortality and stroke rate of hospitals with a history of ≤10 CEs per year was 2.6-fold higher than that at hospitals performing ≥50. (P=.02, test for trend).

The characteristics of the 118 patients who received their CE at the small-volume hospitals were strikingly similar to those at the higher-volume facilities (n=1827), with no statistically significant differences in age, sex, race, comorbidities, clinical characteristics, results of vascular imaging, or surgical technique. The pattern of higher mortality at low volume was similar after logistic regression was used to adjust for these covariates.

Less serious complications of CE were also observed in our cases (eg, hematoma, pneumonia, wound dehiscence, pulmonary embolus, wound infection, and deep vein thrombosis). Of these, hematoma (4.0%) and pneumonia (1.5%) accounted for most of such sequelae. The frequency of these types of complications was also higher in hospitals performing ≤10 CEs in 1993: 12.7% versus 7.4% (P=.04)

Discussion

The benefit of CE in symptomatic patients with high-grade stenosis has been clearly established in the North American

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TABLE 3. Surgical Outcome by Clinical Classification

Classification	All Strokes	Moderate/Severe Strokes	Stroke-Related Death	MI	MI-Related Death
Stroke in evolution (n=9)	0	0	0	0	0
Mild/moderate stroke <3 wk (n=83)	8 (9.6%)	5 (6.0%)	2 (2.4%)	1 (1.2%)	0
Mild/moderate stroke >3 wk (n=148)	7 (4.7%)	4 (2.7%)	3 (2%)	2 (1.4%)	0
Multiple TIAs (n=17)	3 (17.6%)	1 (5.9%)	0	1 (5.9%)	1 (5.9%)
Single TIA (n=686)	26 (3.8%)	15 (2.2%)	7 (1%)	9 (1.3%)	3 (0.4%)
Asymptomatic (n=1002)	24 (2.4%)	10 (1.0%)	2 (0.2%)	8 (0.8%)	6 (0.6%)
All cases (n=1945)	68 (3.5%)	35 (1.8%)	14 (0.7%)	21 (1.1%)	10 (0.5%)

Symptomatic Carotid Artery Trial. CE has been reported to be beneficial in the ACAS clinical trial, although questions have been raised regarding the clinical importance of the conclusions[19,20] as well as their statistical methods.[21] These two studies, along with consensus statements from experienced clinicians, have been the principal sources for determining the appropriate indications for CE. It is not clear that the results from these trials can be extrapolated to the community and nontrial conditions. All of these resources have emphasized that even under optimal circumstances the risk of stroke is significantly influenced by patient selection, the skill of the operating surgeon, and the quality of care provided by the hospital. In this study we examined the pattern of practice of CE in Medicare beneficiaries in unselected hospitals with the objective of defining those areas in which measures might be instituted to improve care.

In Georgia, the survival rate free of either stroke or MI was 94.3%. There was, however, a statistically significant increase of morbidity and mortality as well as an increase in less severe complications in those hospitals performing ≤10 CEs on

TABLE 4. Surgical Volume in Relation to Demographic Factors, Hospital Surgical Volume, and Appropriateness of Surgery

Category	No. (%) of Patients by Category	No. (%) of Patients With Severe Stroke or Death	Odds Ratio (Confidence Interval)
Demography			
Age, y			
0-64	136 (7.0)	1 (0.7)	0.3 (0.0-1.7)
65-74	1109 (57.0)	29 (2.6)	1.0
75-84	631 (32.4)	25 (4.0)	1.5 (0.9-2.7)
≥85	69 (3.5)	2 (2.9)	1.1 (0.1-4.1)
Sex			
Female	910 (46.8)	33 (3.6)	1.0
Male	1035 (53.2)	24 (2.3)	0.6 (0.4-1.1)
Race			
White	1761 (90.5)	51 (2.9)	1.0
Nonwhite	184 (9.5)	6 (3.3)	1.0 (0.4-2.3)
Charlson Index			
Index=0	519 (26.7)	6 (1.2)	1.0
Index>0	1426 (73.3)	51 (3.6)	3.2 (1.4-9.1)
Other factors			
Hospital volume			
1-10	118 (6.1)	7 (5.9)	2.6 (0.9-6.4)
11-25	286 (14.7)	11 (3.8)	1.7 (0.7-3.6)
26-50	428 (22.0)	13 (3.0)	1.3 (0.6-2.7)
>50	1113 (57.2)	26 (2.3)	1.0
Surgery appropriate			
No	74 (3.8)	3 (4.1)	1.0
Yes	1871 (96.2)	54 (2.9)	0.7 (0.2-3.6)

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TABLE 5. Surgical Outcome in Relation to Vascular Factors and Surgical Technique

Category	No. (%) of Patients by Category	No. (%) of Patients With Severe Stroke or Death	Odds Ratio (Confidence Interval)
Vascular factors			
Stenosis			
0-35%	55 (2.8)	1 (1.8)	0.7 (0.1-5.4)
36-55%	101 (5.2)	4 (4.0)	1.4 (0.5-4.1)
56-75%	433 (22.3)	13 (3.0)	1.1 (0.6-2.2)
76-94%	1189 (61.1)	33 (2.8)	1.0
95-100%	167 (8.6)	6 (3.6)	1.4 (0.6-3.5)
Contralateral occlusion			
No	1919 (98.7)	57 (3.0)	1.0
Yes	26 (1.3)	0 (0.0)	0.0 (0.0-5.1)
Ulcer present			
No	1500 (77.1)	39 (2.6)	1.0
Yes	445 (22.9)	18 (4.0)	1.6 (0.8-2.9)
Internal carotid plaque			
None	967 (49.7)	22 (2.3)	1.0
Small	665 (34.2)	24 (3.6)	1.6 (0.9-3.0)
Large	313 (16.1)	11 (3.5)	1.6 (0.7-3.4)
Plaque at siphon			
No	1803 (92.7)	54 (3.0)	1.0
Yes	142 (7.3)	3 (2.1)	0.7 (0.1-2.2)
Surgical technique			
Anesthesia			
Local	294 (15.1)	5 (1.7)	1.0
General	1651 (84.9)	52 (3.1)	1.9 (0.7-6.1)
Shunt Used			
No	814 (41.9)	19 (2.3)	1.0
Yes	1131 (58.1)	38 (3.4)	1.5 (0.8-2.7)
Patch used			
No	1430 (73.5)	47 (3.3)	1.0
Yes	515 (26.5)	10 (1.9)	0.6 (0.3-1.2)

Medicare patients during the year of the study. Surgical volume and mortality after CE were also studied by Segal et al.[22] Although they studied volume of individual surgeons, which our data did not permit, they found a slightly higher mortality at lower-volume hospitals (2.11% versus 1.97%). In contrast to their study, we were able to control for case mix. Moreover, we found a weak relationship between volume and mortality at higher volumes. The largest increase in mortality occurred between the two hospital groups with the lowest surgical volumes.

To determine a more stable estimate of the association between mortality and the frequency of performing CEs in a given period, we combined the 30-day mortality for all cases from 1991 through 1995, using data obtained from Medicare, Part A files. The expanded sample ($n=10\,569$) showed a statistically significant increased mortality rate for hospital performing ≤ 10 CEs per year. (Table 6). This observation further confirms the volume relation we found in our study.

The sharp predominance of white patients over blacks and "others" receiving CE has been reported by others.[23,24] The observation that blacks have less severe carotid artery atherosclerosis may, to a degree, account for this difference.

TABLE 6. Mortality Rates for CE by Hospital Volume of Medicare CE Surgeries, 1991-1995

No. of CEs/y	Average No. of Hospitals	Total No. of Cases	No. (%) of Deaths
1-10	22.6	532	13 (2.4)
11-25	17	1 427	14 (1.0)
26-50	15	2 648	39 (1.5)
>50	12.2	5 962	55 (0.9)
All surgeries		10 569	121 (1.1)

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Although determining the appropriateness of a surgical procedure by retrospective chart review is inherently limited,[25] we found that the overall rate of appropriateness of CE in Medicare patients in Georgia in 1993 was 96%. Although the data imply that there have been changes in the pattern of practice, this higher rate of appropriateness in comparison to previous reports also reflects changes in evidence-based practice guidelines, particularly those concerning asymptomatic patients and early endarterectomy after a nondisabling stroke.

In the validity sample of 50 cases described above, the surgeons had higher rate of appropriateness than did the nonsurgeons. This difference in appropriateness ratings between performers and nonperformers of a variety of surgical procedures, including CE, has been noted by Kahan et al.[26]

The rationale to treat all patients as though they were low risk (see Appendix) is consistent with the fact that the risk score can successfully identify patients with higher risk of complications after surgery but does not address the likely possibility that those patients at high risk may stand to benefit more than those at lower risk. The physician, on the other hand, weighs the risks versus the benefits to identify those for whom surgery would be appropriate. Although other factors may also define the risk of CE (eg, Charlson Severity Index, degree of stenosis, age, and sex), they do not clarify unambiguously who might benefit from the procedure. Sound clinical judgment remains an important factor in deciding which patients will benefit from CE. As shown in Table 3, those patients who were neurologically less stable (a recent stroke or multiple TIAs) had the highest rates of adverse outcomes. The identification of high-risk patients based on thorough risk factor analysis offers an important opportunity to improve the surgical outcome of this procedure.

Matchar et al[27] examined the influence of the estimated perioperative mortality and stroke rate on the assessment of appropriateness of CE. Using a modified version of the Sundt criteria for risk assessment, these investigators found that when the thresholds for surgical risk were placed at values that were defined by an expert panel, only 33.5% of 1160 CEs were classified as "appropriate" when the assigned risk was "high" (5% to 7%). When the risk was assigned as "low" (<3%), 81.5% were classified as appropriate. They concluded, as we did, that appropriateness ratings are highly sensitive to assumptions about acceptable levels of surgical risk. They suggest that the ultimate responsibility rests with clinicians who are informed and accountable for their decisions.

Similar conclusions were reached by Brook et al,[28] who in a discussion of the appropriateness of CE and other procedures concluded that "appropriateness of care cannot be closely predicted from many easily determined characteristics of patients, physicians, or hospitals. Thus for the present, if appropriateness is to be improved, it will have to be assessed directly at the level of each patient, hospital, and physician." The current study supports these premises.

Bratzler et al,[29] using criteria established by a multidisciplinary study group, studied the indications for CE in 774 CEs performed on Medicare beneficiaries in eight hospitals in Oklahoma in 1993 to 1994. They found that 98% of the procedures were documented as being appropriate. In the Oklahoma study, the 30-day survival rate free of stroke was 95%.

Because of the low incidence of serious postoperative complications in the present study, the relationships of various surgical techniques to outcome were not statistically established. A larger study of outcomes now being conducted by the Health Care Financing Administration may provide more robust results. Medicare Part A billing data indicate that in Georgia the number of CEs performed on Medicare beneficiaries has risen from 1696 in 1991 to 2848 in 1995, reflecting similar trends nationally.[22] In view of the increasing frequency of CE, it is important to continue to monitor the patterns of practice of this procedure.

Appendix

Current Indications for CE

Asymptomatic Patients With Carotid Artery Disease: For Patients With a Surgical Risk <3%

1. Proven indications: none*
2. Acceptable but not proven indications: ipsilateral CE for stenosis ≥75% with or without ulceration, irrespective of contralateral artery status, ranging from no disease to total occlusion*
3. Uncertain indications
   - Stenosis <50% with a "B" or "C" ulcer irrespective of contralateral internal carotid artery status
   - Unilateral CE with CABG, CABG required with bilateral asymptomatic stenosis >70%
   - Unilateral carotid stenosis >70%, CABG required, unilateral CE with CABG
4. Proven inappropriate indications: none defined

*On September 28, 1994, the National Institute of Neurological Disorders and Stroke stated that it was halting the ACAS because a clear benefit was evident in favor of surgery in asymptomatic patients with carotid diameter stenosis ≥60%.

Symptomatic Patients With Carotid Artery Disease: For Patients With a Surgical Risk <6%

1. Proven indications
   - Single or multiple TIAs within a 6-month interval or crescendo TIAs in the presence of a stenosis ≥70%, with or without ulceration, with or without antiplatelet therapy
   - Mild stroke within a 6-month interval, in the presence of a stenosis ≥70%, with or without ulceration, with or without antiplatelet therapy
2. Acceptable but not proven indications
   - The presence of unilateral or bilateral stenoses ≥70%, CABG needed
3. Uncertain indications
   - TIA (single, multiple, or recurrent) with stenosis <50%, with or without ulceration, with or without antiplatelet therapy
   - Crescendo TIAs, with or without ulceration, and a stenosis <50%
   - TIAs in a patient who requires CABG and has a stenosis <70%
   - Mild stroke with carotid stenosis <50%, with or without ulceration, with or without antiplatelet therapy
   - Moderate stroke with carotid stenosis <69%, with or without ulceration, with or without antiplatelet therapy
   - Evolving stroke with carotid stenosis <69%, with or without ulceration, with or without antiplatelet therapy
   - Global ischemic symptoms with ipsilateral carotid stenosis >75% but contralateral stenosis <75%, with or without ulceration, with or without antiplatelet therapy
   - Acute dissection of internal carotid artery with persistent symptoms while on heparin
   - Acute carotid occlusion, diagnosed within 6 hours, producing transient ischemic events
   - Acute carotid occlusion, diagnosed within 6 hours, producing a mild stroke

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4. Proven inappropriate indications
- Moderate stroke with stenosis <50%, not on aspirin
- Evolving stroke with stenosis <50%, not on aspirin
- Acute internal carotid artery dissection, asymptomatic, on heparin

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References

1. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade stenosis. *N Engl J Med*. 1991;325:445–453.
2. Mayberg MR, Wilson SE, Yatsu F, Weiss DG, Messina L, Hershey LA, Colling C, Eskridge J, Deykin D, Winn HR. Carotid endarterectomy and prevention of cerebral ischemia in symptomatic carotid stenosis: Veterans Affairs Cooperative Studies Program 309 Trialist Group. *JAMA*. 1991;266:3289–3294.
3. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. *JAMA*. 1995;273:1421–1428.
4. Moore WS, Vescera CL, Robertson JT, Baker WH, Howard VJ, Toole JF. Selection process for surgeons in the Asymptomatic Carotid Atherosclerosis Study. *Stroke*. 1991;22:1353–1357.
5. Committee on Health Care Issues. Does carotid endarterectomy decrease stroke and death in patients with transient ischemic attacks? *Ann Neurol*. 1987;22:72–76.
6. McCrory DC, Goldstein LB, Samsa GP, Oddone EZ, Landsman PB, Moore WS, Matchar DB. Predicting complications of carotid endarterectomy. *Stroke*. 1993;25:1285–1291.
7. Brott TG, Labutta RJ, Kempczinski RF. Changing patterns in the practice of carotid endarterectomy in a large metropolitan area. *JAMA*. 1986;225:2609–2612.
8. Dyken ML, Okras R. The performance of endarterectomy for disease of the extracranial arteries of the head. *Stroke*. 1984;1 5:948–950.
9. Easton JD, Sherman DG. Stroke and mortality in carotid endarterectomy: 228 consecutive operations. *Stroke*. 1977;8:565–568.
10. 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;1 7:370–376.
11. Yates GN, Bergamini TM, George SM Jr, Hamman JL, Hyde GL, Richardson JD. Carotid endarterectomy results from a state vascular society: Kentucky Vascular Surgery Society Study Group. *Am J Surg*. 1997;173:342–344.
12. Winslow CM, Solomon DH, Chassin MR, Kosecoff J, Merrick NJ, Brook RH. The appropriateness of carotid endarterectomy. *N Engl J Med*. 1988;318:721–727.
13. Matchar DB, Goldstein LB, McCrory DC, Odone EZ, Jansen DA, Hillborne LH, Park RE. *Carotid Endarterectomy: A Literature Review and Ratings of Appropriateness and Necessity*. Santa Monica, Calif: Rand Press; 1992.
14. Moore WS. Mohs JP, Naja H, Robertson J., Stoney RJ, Tools, J. Carotid endarterectomy: practice guidelines. Report of the Ad Hoc Committee to 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;15:471–478.
15. Moore WS, Barnett HIM, Beebe HG, Bernstein EF, Brener BJ, Brott T, Caplan LR, Day A, Goldstone J, Hobson RW, II, Kempczinski RF, Matchar DB, Mayberg MR, Nicolaides AN, Morris JW, Ricotta JJ, Robertson J., Rutherford RB, Thomas D, Tools J, Trout HH III, Wiebers DO. Guidelines for carotid endarterectomy: a multi disciplinary consensus statement from the Ad Hoc Committee, American Heart Association. *Circulation*. 1995;91:566–579.
16. Jennett B, Bond M. Assessment of outcome after severe brain damage: a practical scale. *Lancet*. 1975;1:480–484.
17. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chron Dis*. 1987;40:373–383.
18. Fleiss JL. *Statistical Methods for Rates and Proportions*. 2nd ed. New York, NY: John Wiley & Sons; 1981.
19. Barnett HJM, Meldrum HE, Eliasziw M. The dilemma of surgical treatment for patients with asymptomatic carotid disease. *Ann Intern Med*. 1995;123:723–725.
20. Frey JL. Asymptomatic carotid stenosis: surgery's the answer, but that's not the question. *Ann Neurol*. 1996;39:405–406.
21. Barnett HJM, Eliasziw M, Meldrum HE, Taylor DW. Do facts and figures warrant a 10-fold increase in the performance of carotid endarterectomy on asymptomatic patients? *Neurology*. 1996;46:603–608.
22. Segal HE, Rummel L, Wu B. The utility of PRO data on surgical volume: the example of carotid endarterectomy. *Qual Rev Bull*. 1993;19:150–151.
23. Gillum RF. Epidemiology of carotid endarterectomy and cerebral arteriography in the United States. *Stroke*. 1995;26:1724–1728.
24. Horner RD, Oddone EZ, Matchar DB. Theories explaining racial differences in the utilization of diagnostic and therapeutic procedures for cerebrovascular disease. *Milbank Q*. 1995;73:443–462.
25. Leape L, Hilbome LH, Schwartz JS, Bates DW, Rubin HR, Slavin P, Park RE, Witter DM Jr, Panzer RJ, Brook RH. The appropriateness of coronary artery bypass graft surgery in academic medical centers: Working Group of the Appropriateness Project of the Academic Medical Center Consortium. *Ann Intern Med*. 1996;125:8–18.
26. Kahan JP, Park RE, Leape LL, Bernstein SJ, Hilborne LH, Parker L, Kamberg CJ, Ballard DJ, Brook RH. Variations by specialty in physician ratings of the appropriateness and necessity of indications for procedures. *Med Care*. 1996;34:512–523.
27. Matchar DB, Oddone EZ, McCrory DC, Goldstein LB, Landsman PB, Samsa G, Brook RH, Kamberg C, Hilborne L, Leape L, Horner R. Influence of projected complication rates on estimated appropriate use rates for carotid endarterectomy. *Health Serv Res*. 1997;32:325–342.
28. Brook RH, Park RE, Chassin MR, Solomon DH, Keesy J, Kosekoff J. Predicting the appropriate use of carotid endarterectomy, upper gastrointestinal endoscopy, and coronary angiography. *N Engl J Med*. 1990;323:1173–1177.
29. Bratzler DW, Oehlert WH, Murray CK, Bumpus L, Moore LL, Piatt DS. Carotid endarterectomy in Oklahoma Medicare beneficiaries: patient characteristics and outcomes. *J Okla State Med Assoc*. 1996;89:423–429.

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