Carotid endarterectomy. Clinical results in a community-based teaching hospital

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Stroke 1988;19;1323-1327
Stroke is published by the American Heart Association. 7272 Greenville Avenue, Dallas, TX 72514
 Print ISSN: 0039-2499. Online ISSN: 1524-4628

Original Contributions

Carotid Endarterectomy

Clinical Results in a Community-Based Teaching Hospital

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Since 1971, 688 consecutive carotid endarterectomies were performed in 612 patients in a community-based teaching hospital by 16 surgeons; 82% of the procedures were performed in patients who had suffered a transient ischemic attack, amaurosis fugax, or a previous stroke. Seven patients (1%) died, five of perioperative stroke and two of myocardial infarction. Thirty-one patients suffered a perioperative stroke (4.5% of the 688 endarterectomies); 20 patients (2.9% of 688) were left with moderate to severe neurologic deficits. The combined mortality/major neurologic deficit morbidity rate (number of patients ÷ number of endarterectomies) is 3.2%. Both operative mortality and morbidity have progressively declined in successive 5-year periods, with no deaths and a 2.7% stroke rate in 148 endarterectomies performed after 1984. Our results indicate that carotid endarterectomy as practiced in a community-based teaching hospital can be performed without excessive risk. (*Stroke* 1988; 19:1323–1327)

Death and disability related to stroke remain one of the most important public health problems in the United States today. Even though the stroke rate is declining by approximately 6% annually, more than 150,000 Americans die each year of stroke. Many of the estimated 2 million people disabled by stroke are in their economically productive years. The total cost to the nation was estimated at 12.8 billion dollars in 1987.[1]

The role of carotid endarterectomy in the prevention of stroke has come under increasing scrutiny. It is estimated that more than 100,000 carotid endarterectomies are performed annually in the United States, at a cost in excess of 1.2 billion dollars.[2]

Many surgeons have achieved excellent results with low morbidity and mortality rates, and many centers also report excellent results. However, the overall results of surgery may be substantially worse than those reported in the best series. Community-based studies appear to indicate that morbidity and mortality rates, although declining, are still excessive for some groups of patients.[3] Because of allegations of high morbidity and mortality rates, all institutions in which carotid endarterectomy is performed have been challenged to review their results.[4]

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Received February 17, 1988; accepted June 13, 1988.

Subjects and Methods

We reviewed the results of 688 consecutive carotid endarterectomies performed at Baystate Medical Center from 1971 to the present. Virtually all patients were operated on under general anesthesia; shunting was routinely used, as was heparin anticoagulation. Primary closure of the arteriotomy was most commonly employed, although patch closures with autogenous vein or synthetic materials were occasionally used. Endarterectomy was performed under local or regional anesthesia extremely rarely, and other types of monitoring such as intraoperative electroencephalography or cerebral blood flow measurements were not used. Completion angiography was rarely used, and intraoperative ultrasonic imaging was not employed.

Results

There were 688 carotid endarterectomies performed in 612 patients; 76 patients had two operations. We excluded patients undergoing combined carotid and cardiac operations. Of the 688 endarterectomies, 408 (59%) were in men and 280 (41%) were in women. The patients' mean age at surgery was 64.4 (median 65), with a range of 27–87 years. There were 334 (49%) right-sided and 353 (51%) left-sided endarterectomies; one patient underwent bilateral endarterectomy. Five hundred sixty-two procedures (82%) were for symptomatic carotid disease; 126 (18%) were for asymptomatic disease or prophylaxis prior to other major surgery (Table 1).

TABLE 1. Primary Indications for and Incidence of Perioperative Stroke in 688 Carotid Endarterectomies in Community-Based Teaching Hospital

Indication	Indications for endarterectomy		Incidence of perioperative stroke		
	No.	%	Strokes	Incidence (%)	*p*
Symptomatic (n=562)					
Transient ischemic attack	248	36.0	11	4.4	0.90
Amaurosis fugax	173	25.1	5	2.9	0.33
Stroke					
Completed	94	13.7	6	6.4	0.50
Progressive	7	1.0	4	57.1	0.0001
Reversible ischemic neurologic deficit	21	3.1	1	4.8	0.63
Miscellaneous	19	2.8	1	5.3	0.69
Asymptomatic (n=126)					
Asymptomatic bruit	46	6.7	1	2.2	0.67
Prophylaxis for major surgery	6	0.9	0	0.0	0.65
Repair of contralateral side	74	10.8	2	2.7	0.62

Seven patients died, for a gross mortality rate of 1%. Five deaths were directly related to perioperative strokes, and two were caused by cardiac problems. Two of the five stroke deaths occurred in patients undergoing emergency surgery for progressive strokes, and one occurred in a patient with a fixed preexisting stroke. No patient undergoing surgery for asymptomatic disease or for prophylaxis died.

There were 31 perioperative strokes, for a gross stroke rate of 4.5% for the 688 endarterectomies (Table 1). The incidence of perioperative stroke by the primary indication for endarterectomy is listed in Table 1. Eleven of the 31 patients had no or a minimal, nondisabling residual neurologic deficit at discharge; 20 patients (2.9% of the 688 procedures) had moderate to severe deficits (major neurologic morbidity) resulting in long-term disability or death (Table 2). The combined mortality/major neurologic morbidity rate (number of patients ÷ number of endarterectomies) was 3.2%. Patients with progressive stroke were particularly vulnerable to perioperative stroke (4 of 7, 57.1%; $p=0.0001$). Patients with completed stroke also incurred a (nonsignificantly) higher perioperative stroke rate (6 of 94, 6.4%). Patients undergoing surgery for asymptomatic disease or prophylaxis, including patients undergoing repair of a contralateral side subsequent to an original procedure, incurred an overall perioperative stroke rate of 2.4% (3 of 126). The perioperative stroke rate was higher for men than for women (4.7% vs. 3.9%) and for left-sided than for right-sided lesions (5.1% vs. 3.9%), but neither result was significant. Patients older than 80 years of age also had a higher perioperative stroke rate, but the numbers are too small for statistical significance (2 of 18, 11.1%).

TABLE 2. Neurologic Deficit After 688 Carotid Endarterectomies in Community-Based Teaching Hospital

Deficit	No.	%
Absent	4	
Minimal	7	
Moderate	9	
Severe	11	
Total	31	4.5

Number of patients, percent of endarterectomies.

The overall complication rate, including minor complications, is 31.7% (Table 3). Two patients developed perioperative myocardial infarction, three had unstable angina, and eight had significant cardiac rhythm disturbances; 46 patients (6.7%) had significant perioperative blood pressure abnormalities requiring control by vasoactive drugs. Eighty-four patients had minor complications such as hematoma, wound infection, urinary tract infection, and hypoglycemia. Forty-five patients (6.5% of the 688 endarterectomies) had 50 transient neurologic deficits that cleared completely and were not classified as a stroke. These 50 transient neurologic deficits are listed in Table 4. Five patients underwent emergency reexploration because of postoperative neurologic deficits (one had a clearly identifiable problem directly related to the use of an indwelling shunt, and three continued to have cerebral transient ischemic attacks [TIAs] following surgery).

Both the stroke and mortality rates have steadily declined in successive 5-year periods (Table 5). Since 1984, there have been no operative deaths in 148 endarterectomies performed and the stroke rate is 2.7%.

Discussion

The role of carotid endarterectomy in the prevention of stroke has generated a great deal of controversy. Critics decry the lack of prospective randomized studies and point out that the two such studies

TABLE 3. Complications in 688 Endarterectomies in Community-Based Teaching Hospital

Complication	No.	%
Cardiac*	32	4.7
Blood pressure abnormality	46	6.7
Pulmonary embolus	2	<1
Respiratory†	8	1.2
Respiratory failure	1	<1
Stroke	31	4.5
Transient neurologic deficit	45	6.5
Seizure	7	1.0
Carotid sinus dysfunction	1	<1

Number of patients, percent of endarterectomies. Patients with multiple complications are listed more than once.

*Includes myocardial infarction, unstable angina, and arrhythmia.

†Includes bronchitis, pneumonia, and bronchospasm.

TABLE 4. Transient Neurologic Deficits Following Carotid Endarterectomy in Community-Based Teaching Hospital

Deficit	No.
Problems swallowing	1
Speech difficulty	4
Tongue weakness	16
Extremity weakness	12
Facial weakness	7
Vascular headaches	1
Visual disturbances	5
Transient ischemic attack, reversible ischemic neurologic deficit	3
Mild confusion	1

Five patients had >1 deficit.

published have shown high morbidity and mortality rates for surgical patients.[1] On the other hand, numerous retrospective studies have been published reporting personal, institutional, multi-institutional, or regional experience in carotid endarterectomy. These studies have been criticized because of their lack of controls and randomization.[5] Whereas excellent results have been reported from many centers, there is still great suspicion that only the good results of surgery are reported and that there is a much higher operative mortality/morbidity rate for the country as a whole than for specialized centers or for surgeons with vast experience.[6]

The first major randomized study of surgery for extracranial vascular occlusive disease was reported by Fields et al in 1970.[7] A series of 316 patients with TIAs and no neurologic deficits was selected from 1,237 patients randomized to medical or surgical treatment. In 169 surgical TIA patients, there were 13 strokes (7.6%) and six deaths (3.6%) compared with one stroke (<1%) and one death (<1%) in 135 medically treated TIA patients. In another randomized controlled study conducted in 1965 and reported by Shaw et al in 1984,[8] the surgical mortality (15%) and morbidity (25%) rates in the 20 surgical patients were so high that the study was abandoned. It should be noted, however, that both studies showed endarterectomy to be effective in controlling neurologic events in the relevant vascular territory after the immediate perioperative period with its attendant morbidity and mortality had passed.

If carotid endarterectomy is more effective than medical treatment in preventing further neurologic events, the question then becomes what constitutes acceptable morbidity and mortality rates for surgery. On the basis of the Joint Study,[7] Jonas and Hass[9] calculated that an acceptable combined mortality/morbidity rate should not exceed 2.9% to show significant superiority of surgery. Even though 2.9% was calculated from a single study performed when the results of surgery were not as good as they are now, this figure has come to be considered a benchmark against which the results of surgery must be measured. For asymptomatic patients, the criteria should be even more stringent. Chambers and Norris[10] have suggested that the annual stroke rate for asymptomatic patients must exceed 5% for carotid reconstruction to be justified.

Reports from several centers indicate that the results of endarterectomy are improving. In 1977, Easton and Sherman[11] reviewed 228 consecutive endarterectomies performed in Springfield, Illinois; the mortality rate was 6.6% and the stroke rate was 14.5%. The combined mortality/stroke rate for this series was 21.1%, and the authors suggested that these results are likely to be representative of those in many other community hospitals throughout the country. Modi et al[12] updated the Springfield report in 1983 with a study of the next 474 endarterectomies from the same institutions and found a mortality rate of 1.6%, a major stroke rate of 3.8%, and a minor stroke rate of 4.4%; combined major stroke/mortality rate was 4.4%. Modi et al concluded that the better results may be due to better patient selection, better radiologic service, and better perioperative management. In another community-based study reported by Slavish et al in 1984,[13] in 743 endarterectomies the mortality rate was 2.7%, the permanent stroke rate was 1.8%, and the temporary neurologic deficit rate was 3.5%; the overall permanent stroke/mortality rate was also 4.4%.

In a multicenter review from 46 institutions, Fode et al[14] reported 3,328 cases for 1981. There was a 2.5% risk of transient neurologic dysfunction and a 6% chance of stroke or death. The intrainstitutional combined major morbidity/mortality rate varied from

TABLE 5. Mortality and Stroke Rates by Year of Surgery for 688 Carotid Endarterectomies in Community-Based Teaching Hospital

		Stroke		Mortality	
Year	*N*	*n*	Rate	*n*	Rate
<1975	66	5	7.6	0	0.0
1975–1979	150	8	5.3	3	2.0
1980–1984	324	14	4.3	4	1.2
>1984	148	4	2.7	0	0.0

0% to 21%. In a multicenter review from five institutions, the Toronto Cerebrovascular Study Group[15] reported 358 endarterectomies for 1982 with a perioperative stroke rate of 3.9% and a mortality rate of 1.5%. The Group concluded that a 5–6% combined mortality/morbidity rate is to be expected for carotid endarterectomy. The report from Rubin et al[16] of 8,535 endarterectomies indicated a 2.1% stroke rate and a 1.6% mortality rate. Hafner and Evans[17] reported 1,200 cases in a collaborative study from two institutions in Ohio. These endarterectomies were all performed under local anesthesia, with a transient neurologic deficit rate of 0.75%, a permanent neurologic deficit rate of 0.9%, and a mortality rate of 0.67%.

These recent studies have been criticized because they report the work of specialized centers or specialized groups of surgeons and may not reflect accurately the national experience outside these groups or centers. Dyken and Pokras[6] noted that 2.8% of patients undergoing carotid endarterectomy in nonfederal hospitals died. These authors estimated the perioperative stroke rate to be one to five times the mortality rate and expressed concern about this high combined mortality/morbidity rate.

There have been few population-based studies reported. The experience in Cincinnati[3] suggests that operative morbidity and mortality rates have declined as the incidence of carotid endarterectomy has increased. The perioperative stroke rate fell from 8.6% in 1980 to 5.1% in 1983–1984; the operative mortality rate fell from 2.8% to 2.3%. The combined stroke/mortality rate fell from 9.5% to 6.5%. However, 50% of those endarterectomies were performed on patients with asymptomatic carotid disease, and the surgical morbidity (3.7%) and mortality (2.4%) and the combined operative morbidity/mortality rate of 5.3% is considered excessive for asymptomatic patients.

Baystate Medical Center is a 915-bed teaching hospital associated with Tufts University School of Medicine. Baystate Medical Center is the largest hospital in western Massachusetts and provides approximately 40% of the hospital care for a population of approximately 800,000. It serves as a tertiary care center for the region, it is the major provider for indigent patients in western Massachusetts, and its patient population is a good cross section of the community at large. Baystate Medical Center maintains independent residency training programs in a number of specialties including internal medicine, general surgery, radiology, and anesthesiology but none in neurosurgery or neurology. The patients in our study were operated on by 16 surgeons, equally divided between neurosurgeons and vascular surgeons. Even though the background, training, and experience of the 16 surgeons varied considerably, the basic surgical techniques were quite similar.

There was no significant difference in the surgical results between the vascular surgeons and the neurosurgeons. We also found no significant correlation between surgical outcomes and the number of procedures performed. While there is obviously a learning curve for all procedures, the precise number of carotid endarterectomies required to maintain competence has proven to be elusive.[18]

Our study confirms the increasing use of carotid endarterectomy at least in the latter part of the last decade and the early part of this decade. As in Cincinnati, mortality and morbidity rates have declined. The reasons for the decline are not clear, but better patient selection, better perioperative management, better control of blood pressure, and better use of antiplatelet drugs may all play a role.

In our study, endarterectomies performed for asymptomatic carotid disease had a lower perioperative stroke rate (2.4%) than the series as a whole. Those performed for completed or progressive stroke (14.7% of the series) contributed significantly to a higher combined mortality/morbidity rate and had a 2.9% mortality rate and a 9.9% perioperative stroke rate. Three of the seven (42.9%) deaths in our series occurred in this group, and 10 of the 31 strokes were in this group. The role of carotid endarterectomy in the management of patients with progressive stroke is not clear. Goldstone and Effeney[19] suggest that the outcomes of medical treatment are worse than those of surgery and that there is a role for aggressive surgical intervention, even though the mortality and morbidity rates in patients with progressive stroke will be higher than for neurologically stable patients.

In spite of the improvement in surgical results, there has not been a corresponding reduction in the controversy about the role of endarterectomy in preventing stroke because almost all the surgical studies reported have been retrospective and nonrandomized.[5] Furthermore, surgical studies are often not directly comparable because of differing definitions of stroke and differing analyses of other clinical end points.

There have been numerous calls for randomized controlled studies, including some calls for requiring surgeons to participate in such studies as a condition for reimbursement.[20] Even the randomized studies that have been reported are subject to criticism. There is no doubt that a well-designed randomized study would be desirable and that such a study would be more acceptable now than it might have been a decade or two ago. However, many surgeons feel that withholding surgery from symptomatic patients may be unethical and therefore a randomized study in symptomatic patients may be difficult to conduct. Even if such a study is conducted, the argument may not be settled if the recent controversy surrounding the Extracranial-Intracranial Artery Bypass Study is any guide.[21]

Warlow[5] has reviewed the evidence concerning carotid endarterectomy and has concluded that "there is not sufficient data to allow a rational decision as to whether carotid endarterectomy does

or does not increase the duration of survival free of stroke after TIA have developed in the carotid artery territory." Our study does not shed any light on this issue, and it is likely to be a long time before any definitive answers are forthcoming. For the immediate future, it seems clear that carotid endarterectomy will play an important role in the management of patients with extracranial cerebrovascular disease. Our study lends some support to the concept that carotid endarterectomy can be performed in institutions other than major university centers without exposing the public to excessively high morbidity and mortality rates.

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KEY WORDS • cerebrovascular disorders • endarterectomy • epidemiology