A RAND NOTE

Use of Carotid Endarterectomy in Five California Veterans Administration Medical Centers

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Although carotid endarterectomy is a controversial and frequently performed surgical procedure, little is known about the clinical appropriateness of its use in actual practice. Are the majority of procedures performed for highly accepted clinical reasons? We studied the clinical appropriateness of 107 procedures performed on 95 patients in 1981 in five Veterans Administration teaching medical centers. Standards for judging appropriate use were based on the recommendations of a multidisciplinary panel of nine physicians. Fifty-five percent of the procedures studied were judged clearly appropriate, 32% equivocal, and 13% clearly inappropriate. The rate of serious operative complications was 5.6%. These results suggest that carotid endarterectomy is overutilized within at least some segments of the Veterans Administration population.

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CAROTID endarterectomy is performed on patients with symptoms or signs of cerebrovascular disease, such as those with carotid bruits or transient ischemic attacks. Its use is controversial due in part to the fact that only a single randomized, controlled trial has compared its efficacy in preventing strokes or death with that of medical or no therapy—and even that study's result was equivocal.[1] Nonetheless, experts suggest that if carotid endarterectomy is performed with a low operative complication rate, it may be of net benefit by reducing the subsequent risk of stroke.[2]

Despite our limited knowledge of its efficacy, carotid endarterectomy is frequently performed.[3] The number of carotid endarterectomies performed annually in the United States between 1971 and 1982 rose nearly sixfold from 15 000 to 85 000. Also, its rate of use varies widely; among 13 state-sized geographic regions of the United States, the ratio of the highest to the lowest rate was 3.5.[4] Similar variations have been observed among referral patterns of 27 British neurologists,[5] as well as when rates for Canada are compared with those for England and Wales.[2] Still, we know surprisingly little about the clinical appropriateness of the carotid endarterectomies being performed in any of these settings. Are patients being prudently selected for this procedure, and how successful is the operation?

See also pp 2515 and 2566.

To address these questions, we examined medical records from five Veterans Administration (VA) medical centers in southern California. We chose these hospitals as examples of presumed high appropriateness because they are academic centers.

We reviewed 1981 records so that we could borrow the indications for evaluating the appropriateness of carotid endarterectomy that were developed by the Rand/UCLA Health Services Utilization Study (HSUS).[6,7] That study convened a multidisciplinary panel of experts to consider the appropriate use of carotid endarterectomy as of 1981. The 864 appropriateness ratings assigned by the panel constitute our guidelines for evaluating surgical appropriateness of the carotid endarterectomies performed in the five hospitals during 1981.

METHODS

Medical records of patients who underwent carotid endarterectomy during fiscal year 1981 were requested and reviewed for five southern California hospitals: Loma Linda, Long Beach, San Diego, Sepulveda, and West Los Angeles. All sites have surgical residency training programs. Records were examined using the record abstraction format developed by the HSUS. Information was collected concerning the patient's clinical presentation, results of cerebral angiography, presence of

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The opinions expressed herein are not necessarily those of the Veterans Administration.

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and severity of comorbid conditions that might influence the patient's surgical risk, and perioperative complications. Serious perioperative complications were defined as stroke, myocardial infarction, or death occurring within 30 days of carotid endarterectomy.

All information was collected by one of two investigators, one a physician internist (N.J.M.) and the other a fourth-year medical student. Interinvestigator reliability was assessed by comparing appropriateness ratings assigned by each to 11 patients. All charts were examined independently.

Ratings of the appropriateness of 864 potential indications for performing carotid endarterectomy were borrowed from the HSUS and were based on the judgments of nine nationally known experts representing vascular and neurosurgery, neuroradiology, neurology, and general medicine.[6,8] Appropriate was defined to mean that the expected health benefit (eg, increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeded the expected negative consequences (eg, mortality, morbidity, anxiety of anticipating the procedure, time lost from work) by a sufficiently wide margin that the procedure was considered worth performing. Indications were rated on a nine-point scale where 9 represented a highly appropriate indication, 5 an indication that was neither clearly appropriate nor clearly inappropriate, and 1 a highly inappropriate indication. Indications were judged of equivocal appropriateness if median ratings were midrange (4 through 6) or if the panelists disagreed. Disagreement was defined to mean that after one extreme high rating and one extreme low rating had been discarded, at least one of the remaining seven ratings fell in the lowest three-point region (1 through 3) and at least one fell in the highest (7 through 9).

Assignment of ratings was based on knowledge of the patient's clinical presentation, angiography result, and surgical risk. There were 11 possible clinical presentations; six involved transient ischemic attacks (TIAs), two stroke, two asymptomatic patients, and one dementia (Table 1). Twenty-two angiography result categories were considered, 15 in the case of asymptomatic patients. The categories were specified according to degree of diameter stenosis of each carotid artery, presence or absence of an ulcerative lesion, and relationship to the side of symptoms, where applicable. Not all possible combinations of angiographic findings, however, were used to create separate categories. (A complete listing of indications has been published elsewhere.[8]) In general, stenosis was categorized as 1% to 49%, 50% to 69%, 70% to 99%, and 100% occlusion. When the angiography report failed to specify the percentage of stenosis, we attempted to assign patients to the highest conceivable category of surgical benefit by making the following assumptions: (1) "tight" or "high-grade" stenosis was equated with 70% to 99% stenosis; (2) "mild" or "moderate" stenosis was equated with 50% to 69% stenosis; and (3) "minimal" or "normal" was equated with 1% to 49% stenosis.

Ulcerative lesions were specified as multicentric, large, small, or none. When not described as such by an angiography report, the following assumptions were made: (1) an ulceration with multiple caverns was assumed to be multicentric; (2) any ulceration not otherwise described was assigned to the high surgical benefit category of "large ulceration"; (3) only ulcerations specifically described as "small," "in-

Table 1.—Clinical Presentation Categories for 864 Rated Indications for Carotid Endarterectomy

1. Carotid transient ischemic attack (TIA) and/or amaurosis fugax—single attack
2. Carotid TIAs and/or amaurosis fugax—multiple episodes, medical therapy never tried
3. Carotid TIAs and/or amaurosis fugax—multiple episodes with at least one recurrence since initiation of medical therapy
4. Carotid TIAs and/or amaurosis fugax—multiple episodes; no recurrence since initiation of medical therapy (at least 3 mo of therapy)
5. Vertebrobasilar TIA(s)
6. Postatherothrombotic stroke
7. Stroke in evolution
8. Crescendo carotid TIAs
9. Asymptomatic
   - 9A. Asymptomatic, normal stroke risk
   - 9B. Asymptomatic, high stroke risk
10. Asymptomatic, patient to undergo other surgery*
    - 10A1. Intra-abdominal or intrathoracic surgery, normal stroke risk†
    - 10A2. Intra-abdominal or intrathoracic surgery, high stroke risk‡
    - 10B1. Coronary artery bypass surgery, normal stroke risk†
    - 10B2. Coronary artery bypass surgery, high stroke risk‡
11. Dementia of vascular origin

*Implies that carotid endarterectomy is planned prophylactically before patient undergoes other noncarotid surgery

†Normal stroke indicated that risk of stroke is less than 10% within eight years, based on Framingham Study data.[16]

‡High stroke risk indicates that risk of stroke is 10% or greater within eight years, based on Framingham Study data.[16]

Table 2.—Five Sample Indications for Performing Carotid Endarterectomy and Corresponding Appropriateness Indicators

Indication	Appropriateness Category	Median Rating
Patient has carotid transient ischemic attacks (TIAs). There is 100% occlusion of carotid that is to be operated on and that is on side consistent with symptoms. Patient also has low surgical risk.	Clearly inappropriate	1
Patient has vertebrobasilar TIAs. There is 1%-49% stenosis of carotid that is to be operated on and 50%-99% stenosis of opposite carotid. Patient has high surgical risk.	Clearly inappropriate	1
Patient has multiple carotid TIAs and medical therapy has never been tried. There is 100% occlusion of carotid that is on side of symptoms. Opposite carotid is to be operated on and is 70%-99% stenosed. Patient has elevated surgical risk.	Equivocal	6
Patient is asymptomatic but has high stroke risk by virtue of risk factors. There is 70%-99% stenosis of carotid to be operated on. There is 100% occlusion of opposite carotid. Patient has elevated surgical risk.	Clearly appropriate	7
Patient had single TIA. There is 50%-69% stenosis of carotid that is to be operated on and that is on side consistent with symptoms. There is 100% occlusion of opposite carotid. Patient has low surgical risk.	Clearly appropriate	8

significant," or "possible ulceration" were assigned to the "small ulceration" category; (4) "none" was assumed when the angiography report made no reference to evidence of an ulceration. When the angiography report could not be located (two cases), information concerning the degree of stenosis and presence of ulceration was taken from the angiographer's handwritten note, the surgeon's operative report, or the surgeon's discharge summary. When there was disagreement, the angiographer's note was used. Examples of five indications are shown in Table 2. Three surgical risk categories were used, based on a multifactorial index of cardiac risk.[9] We assigned cases to these categories using the Goldman Index and/or the Dripps-American Surgical Association criteria.[10] "Low risk" was equated to the risk observed among Goldman Index class I patients; in Goldman and coworkers' study, 0.7% of class I patients experienced life-threatening cardiac complications and 0.2% suffered cardiac death. "Elevated risk" was equated to Goldman Index class II and III patients. "High risk" was equated to Goldman Index class IV patients.

Appropriateness scores were further adjusted based on ratings for four factors that were assumed to affect the outcome or utility of the operation for the individual: operative complication rates, functional status, age, and life expectancy (Table 3). Although the rating system allowed for the possibility that adjustments for some factors might raise the appropriateness rating, in fact, all were found to lower the rating or to have no effect. Four factors were found to drop ratings to the inappropriate range in almost every case: serious perioperative complications exceeding 8%, severe dementia, judgment that a patient was incompetent to sign surgical consent, and a residual hemiparesis on the side consistent with symptoms These ratings also came from the HSUS.

Table 3.—Mean Adjustment of Appropriateness Scores to Account for Surgical Care and Comorbid Conditions*

Condition	Clinical Presentation	
	Carotid Symptoms	Asymptomatic
Quality of surgical care		
Serious perioperative complications		
3%-5%	0	−6.3
5%-8%	−1.9	−6.7
>8%	−6.4	−6.7
Carotid endarterectomy performed within 3 wk of prior stroke	−5.9	. . .
Patient's functional status		
Nursing home resident	−0.9	−4.5
Severe dementia	−7.0	−6.7
Not competent to sign surgical consent	−7.0	−6.7
Residual hemiparesis on side of current carotid symptoms†	−6.7	. . .
Age and life expectancy		
Age, y		
80-84	−2.1	−6.2
85-89	−3.8	−6.7
≥90	−5.5	−6.7
Life expectancy, y‡		
1-2	−2.0	−5.4
<1	−6.0	−6.6

*Values in table represent the average drop in median ratings of indications that originally received high appropriateness ratings (7 through 9). Values of −6.0 to −9.0 would drop even the highest ratings to the inappropriate range (1 through 3).

†Stroke or carotid transient ischemic attack indications only.

‡Based on presence of a medical condition other than cerebrovascular disease.

Table 4.—Frequencies and Average Percentages of Inappropriate, Equivocal, and Appropriate Carotid Endarterectomies, by Hospital

Hospital	No. (%) of Procedures, by Appropriateness Rating			Mean Appropriateness Rating*
	Inappropriate	Equivocal	Appropriate	
A	0 (0.0)	6 (35.3)	11 (64.7)	7.1
B	3 (20.0)	2 (13.3)	10 (66.7)	6.3
C	7 (23.3)	8 (26.7)	15 (50.0)	5.6
D	1 (9.1)	4 (36.4)	6 (54.5)	5.5
E	3 (8.8)	14 (41.2)	17 (50.0)	6.7
Total	**14** (13.1)	**34** (31.8)	**59** (55.1)	6.3

*On a 1-to-9 scale, with 1 through 3 inappropriate and 7 through 9 appropriate.

RESULTS

Appropriateness

Ninety-five records were reviewed, constituting 86% of all patients undergoing carotid endarterectomy at the five southern California VA medical centers in 1981; four charts had been transferred to other facilities, three were in active use and could not be obtained, and eight could not be located. Twelve patients underwent two procedures; thus, 107 carotid endarterectomies were reviewed. We found perfect interinvestigator agreement when we compared appropriateness ratings at the level of the indication assigned by each of the two abstractors to 11 procedures.

Fifty-five percent of the carotid endarterectomies were judged appropriate, 32% equivocal, and 13% inappropriate (Table 4). Average appropriateness ratings (on a scale from 1 to 9) ranged from 5.5 to 7.1 by hospital; these interhospital differences were not significant ($P>.05$, analysis of variance).

All patients were in one of four major "clinical presentation" categories: carotid TIAs, 53 procedures (49.5%); poststroke, 28 procedures (26.2%); asymptomatic, 24 procedures (22.4%); and vertebrobasilar TIAs, two procedures (1.9%). Seventy-five percent of patients operated on after

Table 5.—Frequencies and Average Percentages of Inappropriate, Equivocal, and Appropriate Carotid Endarterectomies, by Clinical Presentation

Clinical Presentation	No. (%) of Procedures, by Appropriateness Rating			Mean Appropriateness Rating
	Inappropriate	Equivocal	Appropriate	
Carotid transient ischemic attacks	5 (9.4)	8 (15.1)	40 (75.5)	7.1
Poststroke	3 (10.7)	13 (46.4)	12 (42.9)	6.2
Asymptomatic	6 (25.0)	11 (45.8)	7 (29.2)	5.3
Vertebrobasilar	0 (0.0)	2 (100.0)	0 (0.0)	5.0
Total	**14** (13.1)	**34** (31.8)	**59** (55.1)	6.3

carotid TIAs received high appropriateness ratings (Table 5), but only 29% of the asymptomatic patients received such a rating. Average appropriateness ratings on the 1-to-9 scale varied by clinical presentation, ranging from 7.1 for patients with TIAs to 5.3 for asymptomatic patients ($P<.05$, analysis of variance).

Fourteen carotid endarterectomies (13%) were judged to be inappropriate. Six (43%) of the 14 were inappropriate because they involved surgery on a totally occluded carotid vessel. Three inappropriate procedures were on patients with less than 50% stenosis and no significant ulceration of the operated carotid artery. Five of the inappropriate procedures were performed on asymptomatic patients with an elevated surgical risk and whose operated on carotid was less than 70% stenosed.

Comorbidity-Adjusted Appropriateness Ratings

Adjustments of the appropriateness ratings based on the patient's age, functional status, and life expectancy resulted in lower ratings for ten procedures (9.3%) involving eight patients (8.4%). Four ratings dropped based on the patient's age being greater than 80 years; four dropped on the basis of the presence of a significant residual hemiparesis from a previous stroke; one was lowered because the life expectancy of an asymptomatic patient was less than two years due to the presence of a squamous cell cancer in the lung; and one dropped because surgery was performed within one week of the patient's stroke (a situation thought to be associated with an elevated risk of operative complications). In addition, had the appropriateness ratings been further adjusted for the higher than expected operative complication rate, then just 23% of the carotid endarterectomies studied would have been judged clearly appropriate.

Operative Complications

Six patients (5.6% of cases, 6.3% of patients) suffered serious operative complications. Four (4.2%) of 95 patients suffered nonfatal strokes, one as a result of the preoperative cerebral angiography. One patient had an intraoperative myocardial infarction and subsequently died, and one other perioperative death unrelated to stroke or myocardial infarction also occurred. In addition, three patients (3.1%) suffered hypoglossal nerve palsies (partial or total vocal cord paralysis) as a result of the operation. Serious complications occurred in two of the 14 procedures for which the indications were judged to be inappropriate, both involving patients with significant hemiparesis before operation. This compares with one of the 34 procedures performed for equivocal reasons, and three of the 59 performed for appropriate reasons (not significant, χ^2, $P>.05$).

COMMENT

We used 864 appropriateness ratings developed by a national panel to judge the appropriateness of performing 107 carotid endarterectomies in 1981 in five southern California VA medical centers; 55% were judged appropriate, 32% equivocal, and 13% inappropriate. The results reflect the performance of a group of institutions that we assume employ relatively high standards in surgical decision making because they are important teaching institutions.

It is impossible at present to know how the performance of these hospitals reflects community practice; when the Rand/UCLA HSUS has been completed, such a comparison will indeed be possible. Nor can we assess how many patients who would have benefited from carotid endarterectomy went without operation. Nevertheless, these data suggest that there is some meaningful component of overutilization of carotid endarterectomy in these hospitals.

Two groups of patients accounted for the majority of inappropriate procedures. Six procedures were performed on totally occluded carotid arteries, a situation associated with success rates of less than 40%.[11] Five others were performed on asymptomatic patients with an elevated surgical risk and whose operated on carotid was less than 70% stenosed. The efficacy of carotid endarterectomy in preventing stroke in asymptomatic patients with carotid stenosis is the topic of a major multicenter trial currently being conducted by the VA.

Rates of serious perioperative complications range from 0% to 21% in the carotid endarterectomy literature.[7] Statistical models suggest, however, that achievement of rates of about 3% to 4% is essential if meaningful reductions in stroke incidence over a five-year period are to occur.[12] The 5.6% rate reported herein is based on a small sample (90% confidence interval, 1.8% to 9.4%) and could be as low as 1.8% or as high as 9.4%. Had appropriateness scores, however, been adjusted to account for the 5.6% complication rate, as recommended by the national panel, then 77% of the procedures would have been judged inappropriate or equivocal and just 23% appropriate.

The presence of comorbid conditions lowered appropriateness scores moderately. Of the nine cases in which scores dropped, four involved surgery on patients aged 80 years or older. Assessing surgical "appropriateness" on the basis of age is fairly subjective and hardly the exclusive domain of a national panel. Four other uses of carotid endarterectomy, however, concerned patients with a residual hemiparesis, a condition associated with an elevated risk of serious perioperative complications.[13] Indeed, of the four with hemiparesis before carotid endarterectomy, two suffered an intraoperative stroke.

We believe that the standards we used to gauge appropriateness of carotid endarterectomy reflect the mainstream of opinion regarding its appropriate utilization. The ratings' validity and reliability have been demonstrated, and they have been shown to mirror recommendations of the carotid endarterectomy literature.[6] The ratings reflect the views of a multidisciplinary panel that merged the opinions of surgeons and medical specialists.

Although our appropriateness ratings may be sensitive to panel composition and would be strengthened by more data from a randomized, controlled trial, this process offers an

important means of estimating surgical appropriateness for a procedure whose efficacy we do not yet fully understand. Ratings were made anonymously to ensure that they reflected each panelist's true beliefs. All terms were defined precisely, and ratings were made for clinically homogeneous groups. No effort was made to force agreement among panelists.

The panel was also able to render opinion as to how functional ability, age, and life expectancy influence surgical appropriateness. To the extent that the latter are ethical questions or opinions, they fall beyond the bounds of even the best randomized, controlled trial, yet they remain important components of the surgical appropriateness equation.

Results of this study raise the need for careful attention to proper patient selection. Of particular concern are those patients operated on with hemiparesis or 100% occlusion of the operated artery for whom there was considerable evidence in the literature weighing against endarterectomy. Further, we ask whether these VA centers perform a sufficient number of carotid endarterectomies per year to maintain surgical performance. The highest number of carotid endarterectomies performed in these hospitals was 40 in one year. Studies have pointed to the superior surgical performance of high-volume hospitals, one of them suggesting that a minimum of 200 vascular surgery cases per year is important in ensuring optimal surgical performance.[14,15]

The role of studies such as this one should be to focus attention on the importance of critically assessing, especially among the elderly, the appropriateness of performing commonly used medical and surgical procedures. By doing so, we can perhaps improve quality of care.

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