Who doesn't receive carotid endarterectomy when appropriate?

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Objective: **The purpose of this study was to identify clinical and nonclinical factors associated with failure to perform carotid endarterectomy (CEA) in patients with clinically appropriate indications. We analyzed data from a prospective cohort study performed at five Veterans Affairs medical centers. Patients were referred for carotid artery evaluation if they had at least 50% stenosis in one carotid artery, had no history of CEA, and were independently classified preoperatively as appropriate candidates for CEA, according to clinical criteria. The primary outcome was receipt of CEA within 6 months of evaluation. Data were collected by medical record review and interview regarding clinical status, and patient and physician perception of the risks and benefits of CEA.**

Results: **Among clinically appropriate candidates for CEA, 66.8% (n = 233) did not undergo the operation. Compared with patients who did undergo CEA, a greater proportion of these patients had no symptoms (68.7% vs 45.7%; $P < .001$). A twofold greater proportion of patients who did not undergo CEA were in the highest quartile of reported aversion to surgery. Moreover, a fourfold greater proportion were perceived by their physicians to be at less than 5% risk for future stroke without the operation, and more than a twofold greater proportion were believed to experience less than 5% efficacy from the operation by their providers ($P < .01$). In multivariable analyses, four characteristics were significantly associated with whether an appropriate candidate did not receive CEA: asymptomatic disease, less than 70% stenosis, high expressed aversion to surgery score, and low (<5%) provider-perceived efficacy of the operation.**

Conclusion: **Among patients in the Veterans Affairs health care system who are clinically appropriate candidates for CEA, those who did not receive the operation were less likely to have symptomatic disease or high-grade carotid artery stenosis, but were more likely to report high aversion to surgery and to have a provider who believed CEA would not be efficacious. (J Vasc Surg 2004;39:162-8.)**

Over the last two decades there have been numerous observational studies of the pattern of use of carotid endarterectomy (CEA).[1-7] Concern about overuse of the procedure has been a primary motivation for these inquiries. Although appropriateness was assessed differently, in general these studies suggest that the proportion of CEA procedures performed for appropriate reasons has increased over time. However, underuse of a clinically appropriate procedure is of equal concern as overuse. While overuse appears to be a decreasing concern, existing reports provide essentially no insight into either the proportion of patients who are clinically appropriate candidates for the procedure but never receive it or the reasons why such candidates do not receive the procedure.

Multiple factors may influence whether a clinically appropriate patient undergoes CEA. Patients may perceive the risks of the operation to be greater than the anticipated benefits, despite a physician's recommendation for the operation. Perception of risks may be a consequence of previous personal surgical experience or that of family or friends, personal preferences regarding invasive procedures, trust in the medical community and the patient's personal provider, and beliefs and attitudes about health status and life in general.[8] Similarly, despite clinical indications, the provider may perceive that the overall risk-benefit ratio for a particular patient is too great to warrant the operation, may have concerns about the efficacy of CEA in general, or may have other beliefs and attitudes about the usefulness of this surgical procedure.[9]

As a result of a study designed to assess the association between patient race and receipt of CEA, we were able to investigate why patients who are clinically appropriate for CEA do not receive it. In this report we present findings regarding patient and provider characteristics and perceptions regarding the risks and benefits of CEA, as well as the association of these factors with receipt of CEA in appropriate candidates for this surgical procedure.

METHODS

Study design

This is a secondary analysis of data collected from patients and providers at five Veterans Affairs (VA) Medical Centers, in Atlanta, Ga; Durham, NC; Pittsburgh, Pa; Richmond, Va; and St Louis, Mo.[10] The purpose of the original study was to understand racial differences in the use

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Competition of interest: none.

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of CEA. As an observational study, no attempt was made to standardize or otherwise modify the usual practice patterns involved in evaluating a patient for CEA; interpreting imaging studies, including grading of stenosis; or determining recommendations in light of the findings. Information for the study was obtained from the paper and electronic medical records, interviews with the patients, and a questionnaire survey of their providers. Potential patient participants were identified at carotid ultrasonography or Doppler scanning, and enrolled if they met eligibility criteria. Providers who were eligible for the study and were sent a questionnaire were those who had ordered the noninvasive imaging study. At all sites, these providers were also the ones who discussed the results with the patient and determined the next steps, which could include referral to another provider for further evaluation. All participating patients provided written informed consent. The study was approved by the institutional review boards at the five medical centers.

Study population

Between September 1, 1997, and September 30, 1999, 4677 patients who underwent carotid ultrasonography at any of the five sites were screened for study eligibility. Of these, 902 met study criteria; that is, they had at least one carotid artery with 50% or greater stenosis, had not undergone previous CEA, were cognitively able to participate, and were either African American or white (patients of other race or ethnicity were excluded). As patients of the Department of Veterans Affairs health care system, virtually all were men. Seven hundred eight patients (78%) were enrolled. Medical record review and ascertainment of symptom status was completed for 89 of 91 black patients (98%) and 607 of 617 white patients (97%) enrolled in the study. Six-month follow-up contacts were complete for 662 of the 708 study patients (94%).

Of the 3969 patients who were not enrolled, 2726 (69%) were excluded because they had less than 50% stenosis in both carotid arteries, 577 patients (15%) had previously undergone CEA, 274 patients (7%) had poor mental status, 46 patients (<1%) were self-reported to be of race or ethnicity other than white or black, and 152 patients (4%) were excluded for other reasons. An additional 194 patients (4% of those approached) who were otherwise eligible refused to participate; 86% were white.

Candidate appropriateness for CEA

On the basis of a set of clinical parameters delineated by the Rand Corporation (Santa Monica, Calif), each patient's preoperative appropriateness for CEA was determined independent of provider assessment. The clinical parameters, determined by an expert panel, have high content validity and high test-retest reliability, and are internally consistent with survival estimates generated from decision-modeling of CEA and recommendations from randomized controlled trial findings.[11-14] The clinical information used to make these judgments was abstracted from the medical record, and included symptoms such as transient ischemic attack (TIA) or completed stroke, degree of ipsilateral and contralateral carotid artery stenosis, and anticipated operative risk.

Of the 708 enrolled patients, for the study, we included only the 349 patients (49%) who were appropriate candidates for CEA, as determined by these objective, preoperative criteria. Sixty-seven patients (9%) were determined to be uncertain candidates, and the remaining patients (42%) were judged inappropriate for CEA.

Outcome measures

The primary outcome was failure to undergo CEA within 6 months of the diagnostic test, and was defined as a dichotomous variable (1 = no CEA, 0 = CEA).

Key explanatory variables

The potential explanatory variables of interest were the array of patient-based and provider-based factors that theoretically or empirically influence the decision-making process regarding receipt of CEA. Patient-based factors included patient preference for the operation (ie, aversion to the surgery), trust in the physician, prior surgical experience, and perceived health-related quality of life. Provider-based factors were perceived risks and benefits of CEA for the specific patient, including overall preoperative risk, risk for stroke without the operation, and anticipated efficacy of CEA.

Patient-based factors

Patient aversion to CEA. To determine patient potential aversion to CEA, we used responses to a modified standard gamble scenario that had been previously tested in another population of veterans evaluated for CEA.[15] Assessment of aversion involves presenting the patient with the hypothetical situation that he or she is at high risk for stroke and that there are two treatments, CEA (described) and a pain-free medication. The outcome of the therapies is living another 10 years in the current health state, or death where the risk of death from surgery is set at 5% and the risk for death from the medication begins at 50%. Risk for death from the medication is increased or decreased until the patient is indifferent to the therapy used. The resulting score reflects the excess likelihood of death that the patient is willing to tolerate to avoid undergoing the operation, with higher scores interpreted as indicating greater aversion to surgery. The variable was dichotomized at the fourth quartile, or highest level of aversion (0 = first through third quartiles vs 1 = fourth quartile), on the basis of examination of the appropriate scale for modeling this variable.[16]

Trust in physician. To assess patient interpersonal trust in the provider, we used the Trust in Physician scale, an 11-item validated questionnaire.[17,18] The referenced provider was the provider who was responsible for directing the patient's evaluation for CEA, including ordering the initial noninvasive tests, discussing the findings, and making the recommendation regarding CEA.

Previous surgical experience. Inasmuch as previous surgical experiences are associated with willingness to un-

dergo future operations,[15] this experience was determined from patient self-report. A dichotomous variable was created that had a value of 1 if the patient had undergone any previous surgical operation, and a value of 0 otherwise.

Health-related quality of life. Because a patient's perceived quality of life may affect the decisions about therapeutic recommendations involving surgery, we measured general health-related quality of life with the physical health and mental health subdomains of the Medical Outcomes Study SF-12.[19] These subdomains were analyzed as continuous variables.

Provider-based factors

Provider-based factors were derived from provider surveys regarding their patients' risk-benefit profiles for CEA. At the visit, when results of the ultrasonographic examination were discussed, providers completed a survey of standard questions about the risks and efficacy of CEA for the specific patient. The patient's provider responded to the survey for only 88% of patients. However, patients with completed provider surveys were similar in virtually all characteristics to those for whom data were not available.

Perceived operative risk. This variable represented provider assessment of a given patient's likely risk for stroke or death within 30 days after undergoing CEA. This subjectively determined risk was categorized into three clinically meaningful categories, reflecting low risk ($<3\%$), moderate risk ($3\%<5\%$), and high risk ($\geq 5\%$).[20]

Perceived risk for stroke without CEA. For this variable, the provider specified his or her perception of the patient's risk for future stroke during the subsequent year if CEA was not performed. The array of scores was categorized into quartiles.

Perceived efficacy of CEA. For this variable, the provider specified his or her assessment of the efficacy of CEA for the patient, as measured by the percentage reduction in risk for stroke. On the basis of examination of the appropriate scale for modeling, this variable was dichotomized at 5%. However, the cutoff point is also consistent with clinical trials indicating that avoidance of 5% risk for future stroke warrants CEA.

Covariates. As primary covariates we used patient age, race, neurologic status (asymptomatic disease, TIA, or stroke) and objective operative risk. Objective operative risk was determined through medical record abstraction with the protocol developed by McCrory et al.[21] Clinical status was determined at the carotid ultrasonographic examination. Insufficient data were available for patients with completed stroke for either subtyping or determining severity.

Statistical analysis

The primary goal of the analysis was to examine associations between receipt of CEA and an a priori set of variables with multiple logistic regression modeling. This set included variables that represented clinical, demographic, and perceived risk-benefit domains. The first step of the analysis examined bivariate relationships between receipt of CEA and explanatory variables, with χ^2 analysis when the explanatory variable was categorical and with *t* test or Wilcoxon rank-sum test when the variable was continuous.

Because of the limited sample size available for modeling, we further reduced the number of variables in the model on the basis of empirical examination of the a priori variable set.[22] Because of the relatively high correlation between provider-assessed measures, only one provider-assessed measure, anticipated efficacy of CEA, was retained for modeling. With regard to patient-based variables, initial models did not detect a significant relationship between the Charlson comorbidity measure and the outcome variable, and estimated coefficients for other variables did not change markedly in magnitude in comparison of models with and without the comorbidity measure. We therefore omitted the Charlson measure from the final model.

The next step of the analysis was focused on fitting and assessing the final logistic regression model. Variables in this model included site, race, age in years, baseline neurologic status, carotid artery stenosis, operative risk, aversion score, and provider-assessed efficacy of CEA. Age did not satisfy linearity assumptions for the model (ie, linearity in the logit), and was therefore categorized as younger than 65 years, 65 to 74 years, and older than 74 years, to allow examination of differences in these clinically relevant age categories.[16] Provider-assessed efficacy also was not linear in the logit, and was dichotomized at 5%. Interactions were not assessed in the model, because of limitations in sample size. Sensitivity analysis with a generalized estimating equations model was conducted to ascertain whether clustering of providers affected model results.[23] One variable, site, was not included in this model, because providers were nested within site. To ascertain whether missing data had an effect on results, 10 data sets were multiply imputed with PROC MI (SAS Institute, Cary, NC). Logistic regressions were run for each of these 10 data sets, and parameter estimates from these regressions were combined with PROC MIANALYZE (SAS Institute). All statistical analyses were conducted with Windows version 8.2 (SAS Institute).

RESULTS

Demographic and clinical profile. Among the 349 patients who were classified preoperatively as clinically appropriate candidates for CEA, approximately two thirds ($n = 233$) did not undergo the operation during follow-up. Those who did not undergo CEA differed in baseline neurologic status and site of care (Table I). A significantly greater proportion of patients who did not receive CEA had asymptomatic disease, whereas a smaller proportion had either TIA or completed stroke. Eighty-six percent of patients with TIA and 46% of patients with previous stroke had been evaluated within 120 days of the neurologic event.

A provider could be identified for 329 of the 349 patients who were clinically appropriate candidates for CEA. Among the 121 identified providers were 9 cardiol-

Table I. Demographic and clinical characteristics of patients who are appropriate candidates for CEA according to receipt of CEA

Characteristic	*No CEA (n = 233)*	*CEA (n = 116)*	P*
Demographic			
Mean age (y) SD	69.6, 7.7	68.1, 8.1	.11
Black (%)	11.6	9.5	.59
Education ≥12 y (%)	61.5	63.5	.73
Live alone (%)	24.0	26.1	.69
Enrolled as inpatient (%)	15.9	29.6	.004
Clinical			
Neurologic status (%)			<.001
Asymptomatic	68.7	45.7	
Transient ischemic attack	18.0	33.6	
Stroke	13.3	20.7	
Carotid artery stenosis 70%-99% (%)	90.1	94.0	.31
Comorbidity (%)			
Hypertension	85.4	78.5	.13
Cardiac disease (MI, AFib)	42.5	37.1	.36
Diabetes with end-organ damage	17.6	23.3	.25
Diabetes without end-organ damage	17.2	18.1	.88
Peripheral vascular disease	40.8	40.5	1.00
Median Charlson index score IQR	2.0, 2.0	2.0, 2.0	.89
Low operative risk (McCrory Index)	24.5	34.5	.06
Site (%)			<.001
1	6.0	21.6	
2	18.5	13.8	
3	27.0	25.0	
4	15.5	10.3	
5	33.0	29.3	

CEA, Carotid endarterectomy; *MI*, myocardial infarction; *AFib*, atrial fibrillation; *SD*, standard deviation; *IQR*, interquartile range.
*Pearson χ^2, Wilcoxon rank-sum, or *t*-test.

Table II. Patient-based factors that may influence decision to undergo CEA among patients who are appropriate candidates for CEA

Characteristic	*No CEA (n = 233)*	*CEA (n = 116)*	P*
Aversion to CEA score (%)†			.01
0.00-0.25	76.1	88.3	
0.35-0.95	23.9	11.7	
Median trust in physician IQR‡	1.7 1.0	1.7 0.9	.90
Previous surgical operations (%)	85.0	87.9	.52
Median physical health–related quality of life IQR§	38.6 17.8	36.7 18.5	.16
Median mental health–related quality of life IQR§	55.6 11.5	55.6 12.5	.45

CEA, Carotid endarterectomy; *IQR*, interquartile range.
*Pearson χ^2 or Wilcoxon rank-sum test.
†Higher score indicates greater aversion.
‡Lower score indicates more trust.
§Higher score indicates higher quality of life.

ogists, 11 neurologists, 31 general internists, 8 other medical specialists, 12 vascular surgeons, 9 other surgical specialists, 9 physician assistants, and 8 nurse practitioners; 24 providers did not list their specialty. Participating providers had 1 to 51 patients under their care among the patients included in this secondary analysis.

Patient-based factors that influence the decision for CEA. Only one patient-based attitude or belief was associated with not receiving CEA despite clinical appropriateness (Table II). Those who did not undergo CEA reported greater aversion to CEA, with approximately twice as many patients reporting scores in the highest quartile as compared with clinically appropriate patients who subsequently underwent CEA. However, there was indication that patient refusal of the surgical procedure accounted for only 2.6% of patients who did not undergo CEA.

Provider-based factors that influence the decision for CEA. Overall, providers recommended CEA in 106 patients (30.4%) who had been classified independently as appropriate candidates. In the remaining patients, the provider believed that the overall potential benefits of the operation were outweighed by the risks (n = 29), the patient required further examination or the provider believed the decision should be deferred to a specialist (n = 79), or the operation was believed to be unwarranted on the basis of imaging findings (n = 94). In 41 patients the recommendation of the provider could not be determined because the provider did not return the survey. However, characteristics of these patients were similar to those of patients whose provider did return a survey.

Physician perception of patient risk for future stroke and of the efficacy of CEA was associated with having the operation (Table III). Greater proportions of clinically appropriate candidates who did not undergo CEA were classified in the lowest quartile of physician-perceived risk for stroke for the patient if he or she did not undergo CEA and provider-perceived efficacy of the operation was less than 5%. Among patients who underwent CEA, providers perceived that the patient was at greater risk for stroke without the operation and would experience greater efficacy of the operation if received.

The level of provider-perceived operative risk for the patient was not associated with who did or did not receive CEA. Of note, the level of preoperative risk as determined with the McCrory index and that of the provider were correlated, but not perfectly. Thus 34% (n = 69) of 206 patients who were rated at low risk with the McCrory index were rated at high risk by the physician, whereas 63% (n = 52) of 83 patients categorized at high risk with the McCrory index were judged at lower risk by physicians.

Multivariable model results. After adjustment for covariates, several patient characteristics were important determinants of whether an appropriate candidate did not undergo CEA (Table IV). These characteristics included symptom-free disease, less than 70% stenosis, expressed aversion to surgery that was in the highest quartile of

Table III. Provider-based factors that may influence decision to undergo CEA among patients who are appropriate candidates for CEA according to receipt of CEA*

Perceived characteristic of patient at carotid ultrasound study	*No CEA (n = 198)*	*CEA (n = 110)*	P†
Operative risk			.59
≥5.0%	36.1	32.1	
3.0%-<5.0%	30.1	35.9	
0.0%-<3.0%	33.9	32.1	
Risk for stroke without CEA‡			<.0001
≥15%	18.5	38.0	
10%-<15%	19.5	34.3	
5%-<10%	29.7	19.4	
0%-<5%	32.3	8.3	
Efficacy of carotid endarterectomy			.002
≥5.0%	71.7	88.5	
<5.0%	28.3	11.5	

CEA, Carotid endarterectomy.
*Based on 88% of patients for whom provider returned the survey.
†Pearson χ^2 test.
‡Quartiles arranged from highest to lowest.

Table IV. Adjusted odds ratio* of not receiving CEA, associated with demographic and clinical characteristics of patients who are clinically appropriate candidates for CEA and provider-perceived risks and benefits of CEA

Characteristic	*OR*	*95% CI*	P
Demographic			
Age (y) (referent = <65 y)			.26
65-74	1.8	0.9, 3.6	
≥75	1.6	0.7, 3.6	
Black (referent = white)	0.6	0.2, 1.6	.31
Clinical			
Neurologic status (referent = TIA)			.01
Stroke	1.7	0.7, 4.3	
Asymptomatic	3.7	1.5, 9.1	
<70% Stenosis† (referent = ≥70%)	3.2	1.1, 9.5	.04
Low McCrory index of operative risk (referent = high)	1.1	0.5, 2.6	.75
Perceived risk and benefit			
Aversion score, highest quartile (referent = lower 3 quartiles)	2.3	1.0, 5.1	.04
Low (<5.0%) efficacy of CEA (referent = ≥5.0%)	2.7	1.2, 5.9	.02
Other			
VA facility (referent = Site 5)			.03
Site 1	0.3	0.1, 0.8	
Site 2	1.4	0.6, 3.4	
Site 3	1.4	0.6, 3.1	
Site 4	1.4	0.6, 3.3	

CEA, Carotid endarterectomy; *OR*, odds ratio; *CI*, confidence interval; *TIA*, transient ischemic attack.
*Multivariable logistic model included site, race, age in years, baseline neurologic status, carotid artery stenosis, operative risk, aversion score, and provider-assessed efficacy of CEA. C statistic for logistic regression model = 0.73. Final n for adjusted model = 253.
†Carotid artery stenosis of the artery deemed most appropriate according to the RAND algorithm.

scores, and low (<5%) provider-perceived efficacy of the operation. Among study sites, at only one did the relative odds of appropriate candidates not receiving the operation differ such that relatively few appropriate candidates did not undergo the operation. Sensitivity analyses confirmed that neither clustering nor missing data affected model results.

DISCUSSION

We have documented that certain clinical features and patient reported level of aversion to surgery are significantly associated with whether a clinically appropriate candidate for CEA ultimately undergoes the operation. Specifically, patients who are symptom-free, have carotid artery stenosis less than 70%, are perceived by the provider as likely to experience low efficacy from the operation, and are more averse to surgery have a lower likelihood of subsequently undergoing CEA despite being clinically appropriate candidates.

These findings were derived from an observational study of actual practice patterns related to use of CEA. Previous observational studies have focused on the clinical characteristics of patients who undergo CEA, and specifically on the proportion of patients who are appropriate, inappropriate, or uncertain candidates for the operation.[1-7] Findings from these studies suggest that an increasing proportion of patients receiving CEA are appropriate candidates for the procedure, diminishing concerns about its possible overuse. By contrast, we examined potential underuse of the operation, an area that has not been well studied. We found that a substantial proportion of clinically appropriate candidates (66.8%) do not undergo CEA.

It is interesting that the clinical characteristics associated with receipt of CEA when inappropriate are often similar to those associated with failure to receive the operation when determined preoperatively to be appropriate. That is, a recent report indicates that among the reasons a patient inappropriately receives CEA is the presence of minimal stenosis and extensive comorbidity.[7] By comparison, we found that lower-grade stenosis and lack of symptoms were associated with not receiving CEA when the patient is an appropriate candidate (as determined independently of provider assessment).

Of significance, patient demographic factors and patient attitudes and beliefs about CEA (with the exception of aversion to surgery) had little relationship to undergoing CEA when appropriate. The finding of no association with patient race is important, because a substantial racial difference has been reported in the use of CEA.[24-27] There has been particular concern that the patient-provider decision-making process inappropriately excludes black patients from CEA despite the appropriateness of the operation.[15,28] Our findings provide further indication that less use of CEA in black patients may be due, in part, to aversion to surgery rather than to race per se.[10,15]

It is also notable that few of these candidates who were appropriate for CEA refused to undergo the operation. Moreover, provider perception of the efficacy of the operation for the patient was an important factor in whether the

patient subsequently received CEA. While these findings suggest that physicians have the more dominant role in determining the course of care, patients may not be without influence in the decision-making process. Clearly, our findings suggest that patient level of aversion to surgery is involved in the final decision. Although we did not ascertain whether patient aversion to surgery was overtly or more subtly expressed to the physician, clinically appropriate patients who reported the highest level of aversion to surgery were less likely to undergo CEA, after adjustment for other potential influences on the decision. This is an area that may require further investigation to determine the extent to which patient aversion to surgery influences the final decision regarding CEA.

These findings and their interpretation need to be considered with due regard for the limitations of the study. This study was conducted within the Department of Veterans Affairs health care system. This is an equal-access system for eligible patients, and there are fewer cost considerations for patients or physicians in use of health care. That is, patients have minimal responsibility for the cost of their care, and physicians have fewer financial incentives regarding use of surgical procedures. Thus, the patterns observed in this health care system may not reflect patterns in other health care arrangements where cost may be a factor. A related limitation is that patient use of health care within the community was not assessed. Thus, appropriate candidates who did not undergo CEA in VA facilities may have received the surgery from their community provider. Although the exact proportion is not known, we believe it is minimal, especially for expensive procedures, given the cost incentives associated with receiving care within the VA system. A third potential limitation is that virtually all of the patients were men. Men and women may differ in either self-perceived or physician-perceived risks and benefits of CEA. Hence the factors that we identified as associated with receipt of CEA in clinically appropriate candidates may differ in a general population. Another important limitation is that patients were identified at the point of referral for evaluation of carotid arteries. If there was patient selection bias before this point, our cohort may not represent the population of clinically appropriate candidates for CEA. Again, this may bias the array of factors identified as important influences on receipt of CEA.

With due regard for these limitations, we conclude that among patients in the VA health care system who are clinically appropriate candidates for CEA, those who actually undergo the operation are determined primarily by the presence of definitive symptoms (TIA) and signs (high-grade stenosis in the carotid artery), provider-perceived efficacy of the operation for the patient, and patient inherent aversion to the procedure.

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