1990

The risk of carotid endarterectomy in the elderly : an application of claims based research

Neil Andrew Solomon
Yale University

THE RISK OF CAROTID ENDARTERECTOMY IN THE ELDERLY
AN APPLICATION OF CLAIMS BASED RESEARCH

Neil Andrew Solomon

1990

The Risk of Carotid Endarterectomy in the Elderly

An application of claims based research

A Thesis Submitted to the Yale University
School of Medicine in Partial Fulfillment
of the Requirement for the Degree of
Doctor of Medicine

by

Neil Andrew Solomon

1990

ABSTRACT

THE RISK OF CAROTID ENDARTERECTOMY IN THE ELDERLY AN APPLICATION OF CLAIMS BASED RESEARCH

Neil Andrew Solomon

1990

Although carotid endarterectomy is commonly performed, controversy exists over its risk relative to its benefit. To elucidate risk factors for surgical complications, I reviewed Medicare claims files for 2089 New England residents over the age of 65 who underwent carotid endarterectomy in 1984 and 1985. Patients over the age of 70, who comprised two thirds of the sample, faced an average three-fold increased risk of operative death compared to younger Medicare patients. Also, a patient was almost three times more likely to die after undergoing carotid endarterectomy at a hospital performing few of these operations relative to high surgical volume facilities. Similarly, the risk of post-operative stroke was directly related to age and inversely related to surgical volume. The identification of these risk factors helps to clarify the settings under which carotid endarterectomy may offer more threat than benefit. Further research is needed to clarify the causes of the identified correlations. This study also evaluates the ability of the claims data to review outcomes of the operation.

Table of Contents

Introduction

Carotid endarterectomy surgery offers one treatment strategy to reduce the likelihood of stroke in patients with atherosclerotic disease. The surgery, however, has never been evaluated in a satisfactory way to clarify who, if anyone, stands to benefit from this approach compared to medical management. Factors that must be considered in balancing the risks and benefits of the operation include its efficacy and its complication rate. In this study, risk factors for surgical complications are examined and subsequently considered in the medicine-versus-surgery controversy.

Stroke: the scope of the problem

While the incidence of stroke has declined in the United States in recent decades,[1] it remains a widespread, debilitating and expensive medical problem. Today, stroke is the third leading cause of death in the United States,[2] behind only cardiovascular disease and cancer. In 1980, more than 150,000 Americans over the age of 65 died of stroke.[3] The disability associated with the 1.9 million non-fatal events annually,[4] including paralysis, sensory deficits, and aphasias, adds substantially to the collective emotional and financial burden. The greater than $5 billion cost of stroke care in the

US each year[5] reflects the enormity of the problem. Because there exists no proven therapy for strokes once they have occurred, the major thrust of treatment consists of prevention.

Atherosclerosis in the extracranial arteries causes over half of all strokes,[6] and approximately 75% of these cerebral infarctions occur in the carotid distribution.[3] Other causes of stroke, including cardiac embolus, subarachnoid hemorrhage, intracranial hematoma, infection, arteritis, and all events in the vertebral-basilar system, are not potentially correctable by endarterectomy and therefore fall outside the scope of this study.

Risk factors for atherosclerotic stroke

Several risk factors for atherosclerotic strokes including hypertension,[7] diabetes,[8] and hyperlipidemias[9] have been identified. Lifestyle[10,11,12] and diet[13] changes in the population appear to have contributed to the declining stroke rate. Even with improved control of these chronic risk factors, a large number of individuals remain at elevated risk.

Two large epidemiologic studies associated asymptomatic cervical arterial bruit with increased likelihood of subsequent stroke,[14,15] indicating a risk of 2 to 4 times over that of persons without audible bruit. Both research teams concluded, however, that the bruit is a non-focal sign that does not correlate well with the laterality of subsequent cerebral events. Moreover, death in both cohorts was most likely due to heart disease, not stroke. Similarly, a

third study demonstrated a 4% annual incidence of neurologic symptoms in patients with a mid-cervical bruit and no history of such symptoms.[16] When stroke was the only event considered, the yearly rate was less than 2%.

Transient ischemic attacks (TIAs) pose another well established risk factor for stroke. Surveillance of the population of Rochester, Minnesota over a fifteen year period documented an increased risk of stroke and death in people with TIAs.[17] Others have since corroborated this finding.[18,19,20,21] In a twenty year retrospective review of the same city, Cartlidge and co-workers demonstrated that the risk of death at one month after the first TIA is 10 times greater than that in a matched population, but drops thereafter to reach a risk of 1.5 times that of controls after two years.[22] The risk of stroke in the same population was markedly elevated over the expected rate in this community--17.5 times the expected rate at one year, and 9 times the expected rate by the completion of the study (6 to 20 years of follow-up). Like the epidemiologic investigators of asymptomatic bruits, these researchers found a high rate of cardiac events.

Also noteworthy are the findings in the placebo arm of the Canadian Cooperative Study Group's randomized controlled trial of anti-platelet therapy for patients with a prior stroke or recent TIA.[21] This team found a cumulative probability of stroke or death of 29% three years after inclusion in the study. This may not represent a realistic estimate of the risk of stroke after TIA, however, because the cohort included patients with prior strokes in addition to those with TIAs. Although the literature offers widely

varying estimates of stroke and death from cerebrovascular disease due to differences in methodology, it is clear that asymptomatic bruits and especially TIAs identify people at increased risk for stroke and death.

Two other groups may be at heightened stroke risk as well. First, patients with prior strokes may be at increased risk for subsequent events.[23] Secondly, some argue that patients with severe carotid stenosis identified solely by radiographic studies are more prone to have strokes.[24]

Medical management

It is primarily in the two major at-risk populations--patients with carotid bruits and those with TIAs--that medical and surgical interventions to reduce strokes have been investigated. Anti-platelet therapy has become the mainstay of medical protection in patients with carotid artery disease. Several studies of prophylactic aspirin have been conducted,[20,21,25,26] and the consensus from these trials is that a 25 to 30 percent reduction in the incidence of stroke after transient ischemic attacks can be achieved on a daily oral dose of 1300 mg.[2] Examinations have also been made of supplemental platelet anti-aggregants such as sulfinpyrazone[21] and dipyridamole.[27] These studies have found no beneficial effect of substituting or adding a second agent to daily aspirin. Anticoagulation therapy is generally shunned as prophylaxis for at-risk patients because of its increased

incidence of hemorrhagic compications.[28,29,30] As mentioned above, the control of other risk factors such as hypertension, diabetes and hyperlipidemia is another important part of stroke prevention.

Surgical management: carotid endarterectomy

The alternative strategy to manage the patient with stenotic carotid arteries is surgery. Two operative approaches have been attempted, but one, the technique of extracranial-intracranial bypass surgery, has been largely rejected clinically since a large randomized trial failed to demonstrate any benefit of the procedure.[31] The remaining operation for the prevention of stroke due to carotid disease is the endarterectomy.

Carotid endarterectomy is commonly performed, costly and controversial. In 1987, more than 80,000 of these operations were performed in the United States, marking a doubling in surgical volume over 10 years (Table 1). While the volume of endarterectomy has leveled off and even decreased since the middle of the 1980s, it remains one of the most common operation performed in the US.[32] In an era of burgeoning financial consciousness in the health care field, the greater than $1 billion price tag that these operations carry collectively[32] cannot be ignored.

TABLE 1: CAROTID ENDARTERECTOMIES IN THE US BY YEAR*[33,34]

Year	Operations
1972	16,000
1975	34,000
1978	42,000
1981	73,000
1982	82,000
1983	95,000
1984	103,000
1985	107,000
1986	83,000
1987	81,000

*Estimated to the nearest thousand. Includes endarterectomies of the head and neck performed in non-governmental acute care hospitals in the United States.

Disagreement over the role of endarterectomy exists because the scientific evidence currently available is inconclusive and incomplete. In order to evaluate the operation's benefit relative to its risk, several factors must be considered. First, the surgery must be demonstrated to reduce the risk of stroke. To date, the results of two randomized trials on this question have been published.[35,36] The Joint Study,[35] completed twenty years ago, reported a 9% reduction in aggregate stroke and deaths for patients with TIAs who received the operation--17.3% for surgical patients versus 26.2% for the non-surgical arm. The patients were similar in the two groups in meaningful prognostic criteria such as age and distribution of prior TIAs. Patients were followed for an average of 42 months post-randomization and their deficits were well characterized. The non-surgical limb of the trial, however, did not receive aspirin, the currently accepted medical alternative. Consequently, the efficacy of surgery relative to its alternatives may not be

as great as the autors reported. Moreover, The Joint Study considered the long term effects in the surgical limb only in those patients who survived their endarterectomy without neurologic complication. As a result, a subset of patients who may have been at greater risk of suffering strokes in the future were not observed. The other published randomized trial was terminated prematurely due to the increased risk of death observed in its surgical arm.[36] Surgical efficacy from that experiment could not be determined.

If one assumes that carotid endarterectomy can reduce the incidence of stroke due to carotid disease, the risk of the procedure itself must be weighed against that benefit. Along with the inherent dangers of any surgery--including hemorrhage, infection, cardiac stress, and the risks of anesthesia--carotid endarterectomy carries the potential for causing strokes, due either to hypoxic or embolic causes. Several variations in the standard technique have been advocated to reduce the risk of these untoward events--selective shunting, performing the procedure under regional anesthesia, monitoring with electro-encephalography, and closing the artery with a patch graft. All of these modifications appear to be capable of yielding low complication rates, but none has been shown to consistently outperform the standard anesthetic, monitoring and surgical methodology.[37]

Over two hundred studies of the operative mortality and morbidity of carotid endarterectomy have been published during the last fifteen years, reporting death plus stroke rates ranging from less than 3% to greater than

20%.[38,39] Tremendous disparity in the quality of research design appears when reviewing this literature, and many factors contribute to the wide discrepancy in outcomes reported. First, case mix varied widely, both among and within studies. Not only do medical comorbidities influence outcome, but also the literature suggests that patients with tighter stenoses, ulcerated plaques, and prior neurologic symptoms or evolving strokes have a greater chance of complications.[23] Few studies adequately describe their study population to allow for comparison.

Differences in techniques of analysis and reporting of the results consititute a second major set of reasons for the variations in reported outcomes. Because none of the studies, with the exception of the two trials discussed above,[35,36] randomized patients, and most of them were performed in a retrospective fashion, issues of bias cannot be ignored. Many published studies lack explanation of patient selection criteria, descriptions of the method and period of follow-up, and clear definition of outcomes.[*] Moreover, the diagnosis of stroke remains problematic, with much interobserver variability even among trained neurologists.[40,41]

Almost without exception, the self-reports of individual surgeons or single institutions[42,43,44,45] tend to have lower rates of complications than regional or multi-center studies conducted by independent auditors.[46,47,48,49,50]

---

[*]The response of one major researcher in the field when asked how he defined stroke in his study population underscores just how unscientific the reporting can be: "A stroke is like pornography, you know it when you see it."

This discrepancy may be due to the multitude of potential biases associated with reporting one's own data. Alternatively, the difference in reported outcomes between the single center and multi-center studies may represent the difference between the efficacy and the effectiveness of the procedure: that is to say, the difference between the operation's outcomes under ideal conditions and the realistic expectations of its performance under commonly encountered conditions.

Publication selection biases may be present as well. Only those authors with highly successful outcomes are likely to offer their results for scrutiny. In addition, journals are often more willing to publish "positive" findings than less successful results.

Complications of carotid endarterectomy other than stroke and death are rarely addressed in this vast literature. Between 10 and 20% of patients suffer cranial nerve palsies of the hypoglossal, glossopharyngeal, recurrent laryngeal, superior laryngeal or marginal mandibular nerve.[51,52,53] Most clinicians perceive these impairments as minor nuisances relative to a stroke.

A small percentage of carotid arteries have been shown to restenose after surgery. Studies of symptomatic restenoses reveal a wide spectrum of rates, ranging from 1% to greater than 15%.[54,55,56,57,58] Differences in detection techniques (of the symptoms and of the anatomical lesions) and in the length and rigor of follow-up probably account for the variation in findings as much as differences in surgical proficiency. Patients who restenose derive, at best, temporary benefit from the operation.

Cardiac events constitute a dangerous set of complications of the operation. Because atherosclerosis is a systemic disease, patients with stenotic carotid arteries are likely to have diseased coronary arteries, too. Consequently, myocardial infarction (MI) occurs in a small but not insignificant percentage of endarterectomy patients. A retrospective study of 491 patients found that 3.3% of patients suffered an MI after endarterectomy, and that 1% of all patients died from MI in the immediate post-operative period.[59] There was a ten-fold increase of MI in the patients with prior heart disease (defined as history of angina, congestive heart failure, arrhythmia, prior MI, or use of cardiac medications) versus those without such risk factors. The rates of MI and fatal MI were identical to those quoted above in a separate study published four years later.[60] The latter work showed slightly less than three times the risk of MI in patients with known coronary artery disease, either by history or found on EKG alone, as compared to those lacking coronary artery disease. Neither study considered the rate of MI in a matched cohort that did not receive the surgery.

Evaluating the options available to the at-risk patient

Clinical uncertainty about the appropriate indications for the procedure is reflected in the high degree of regional variation in the utilization rates of carotid endarterectomy.[61,62] For example, residents of Boston are more than

twice as likely to undergo carotid endarterectomy as are residents of New Haven.[63] In the absence of compelling results from a prospective randomized study of the operation's value, researchers have created alternative frameworks to evaluate endarterectomy's place in stroke prevention.[64,65,66,67]

Matchar and Pauker applied a Markov decision analysis to the question of whether an otherwise healthy sixty year old with a recent TIA should undergo carotid endarterectomy.[66] They found that three factors could strongly influence the choice of management: surgical risk, surgical efficacy and the natural history of the disease as reflected in stroke rate without surgery. By looking at each of these key variables at the extremes of their plausible ranges (derived from a critical review of the literature), they created multiple permutations of their decision model. Only when the model was weighted to prefer surgery--based upon the high risk of stroke without endarterectomy and the most optimistic estimate of surgical efficacy--could a benefit (of four additional months of "quality adjusted" life expectancy) be shown for low risk surgery (defined therein as a 1% mortality and 4% non-fatal stroke rate). The balance tipped in favor of medical management when their high estimate of surgical risk (4% mortality, 8% non-fatal stroke) was substituted. No threshold analysis* of surgical risk was included in their publication. When the model was altered to assume

---

*The value at which the computed benefits of both treatment options are equal.

low surgical efficacy (20% of strokes prevented, instead of 50%) or to include a risk of stroke without surgery of 3% per year (instead of 5%), as is estimated for asymptomatic patients,[14,15,16] the relative benefits of either therapy were negligible (a "toss-up") or medical management was clearly preferable to surgery.

Possible risk factors for complications in carotid endarterectomy

Matchar and Pauker's analysis highlights the importance of the surgical complication rate in deciding whether or not to operate. Clearly, that surgical risk varies both among patients and across providers (surgeons and institutions). It is not surprising, therefore, that many clinicians argue that carotid endarterectomy should be restricted to specialized centers or to those with documented operative stroke plus death rates of 5 or 6%.[23,68,69]

A decade ago Luft and colleagues suggested that major surgical procedures be regionalized to "centers of excellence." The argument is based on the assumption that outcomes are better where a procedure is performed more frequently; empirical evidence supports this notion.[70] Observed relationships between volume and outcome may be due to honing skills but may also represent patient selection biases. The volume-outcome relationship has been explored for carotid endarterectomy in several studies. Two studies found no correlation between hospital size and outcomes,[71,72]

whereas a third investigation identified lower complication rates in hospitals with greater than 700 beds as compared to smaller institutions.[46]

The risk of all surgery is generally considered to rise with age. Specifically for endarterectomy, however, three studies found no significant increased risk in patients over the age of 75 or 80, compared either to a younger cohort or to a matched elderly group managed non-surgically, and advocated the use of the procedure in elderly patients.[73,74,75]

The use of claims data to study carotid endarterectomy

With the introduction of easily accessible, powerful computers during the last decade, large data bases of clinical information were assembled and their analytic manipulation became common. At the same time that researchers were discovering the use of data sets to evaluate the clinical practice of medicine, policy-makers were becoming increasingly concerned about the cost of health care. With interests in both cost and quality, the attention of the Health Care Financing Administration (HCFA), the federal agency responsible for managing the Medicare program, has turned toward methods to review the care that it funds.[76] Not only does the HCFA have an interest in using large information data bases to evaluate medical care, the agency has the data itself to probe these issues.

Whenever a Medicare-eligible patient is discharged from any hospital in the US (except a Veteran's Affairs hospital), the HCFA is billed using a

standardized claims form that records, among other things, the patient's age, principle diagnoses (up to five), principle procedures (up to 3), dates of admission, discharge and first procedure, and discharge destination. The diagnoses and procedures are coded according to a standardized classification scheme, the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM).[77] These Medicare billing records are stored in the HCFA Medicare Provider Analysis and Review (MEDPAR) file.

A separate set of data, the Health Insurance Skeletonized Eligibility Write-off (HISKEW) file, maintains information on whether a beneficiary has died and is therefore no longer eligible for Social Security benefits. Each death is dated and recorded regardless of whether the person died in a hospital. A third set of data maintained by the HCFA, the Provider of Services (POS) file, describes characteristics of all institutions that offer services to Medicare beneficiaries.

All the files listed above may be linked for analytic purposes, and specific records may be concatenated to create chronological expressions of a person's in-hospital care. An early example of the use of this technique is the study performed by Wennberg, et.al., to examine complications following prostatectomy.[78]

In the study reported here, the Medicare claims files for the six New England states were used to consider the effects of patient age and surgical volume (by institution) on the complication rate of carotid endarterectomy.

The question of whether such information could be used to help evaluate the performance of carotid endarterectomy at individual hospitals was also explored.

The Medicare claims files are a useful tool to investigate these issues because they allow for access to a large series of cases performed across an entire region, because they provide excellent follow-up beyond the discharge date of the initial hospitalization, and because they report on the majority of patients who receive the operation. Seventy percent of the patients receiving carotid endarterectomy are 65 years of age or older.[34]

Methods

<u>Data source</u>. Data for the current study were obtained from the MEDPAR, HISKEW, and POS files maintained by the HCFA.

<u>Selection of the Study Population</u>. All 2171 hospital discharge abstracts submitted for New England resident Medicare beneficiaries 65 years of age and older discharged between April 1, 1984 and June 30, 1985 who underwent carotid endarterectomy (ICD-9-CM code number 38.12) were reviewed. After eliminating the 81 patients who received surgery outside New England and 1 patient with inconsistent coding, 2,089 patients were selected for inclusion in the study.

<u>Observation Period</u>. The post-operative period was defined as thirty days from the date of endarterectomy. In the MEDPAR file at the time of this study, only the primary procedure was dated. If the endarterectomy was not listed as the primary procedure (n = 83, 3.8% of cases), the date of surgery for the index endarterectomy* was assigned to the midpoint of the hospital

*"Index endarterectomy" denotes the first endarterectomy, regardless of how many of the procedures the patient received. The "index hospitalization" refers to the admission during which the index endarterectomy was performed.

stay. (All reported analyses were repeated using the date of admission as the date of surgery for these 83 cases; none of the analyses were affected.) If a patient received more than one endarterectomy, either on the same artery or the contralateral side, and regardless of whether they were performed during the same hospitalization, all analyses were performed assuming the post-operative period included the 30 days after the first procedure.

<u>Outcomes</u>. Deaths were determined by searching the HISKEW file. Stroke was ascertained by inference from the diagnostic codes recorded on the discharge abstracts in the MEDPAR file.

Two sets of problems arose in identifying post-operative strokes. Some codes describe conditions that may be present in victims of strokes of the carotid distribution, but also are found in other conditions (eg. ataxia). Only those codes that were considered hallmark sequelae of carotid strokes were included in the codes identifying stroke (see Appendix A). Second, because diagnosis codes are neither entered onto the abstraction forms in chronological order nor dated, in several cases ambiguity existed over the temporal relationship of the stroke to the surgery. Timing the stroke is problematic because in some cases the decision to operate may be based upon a prior stroke.

To address this problem, I developed two algorithms (described in Appendix B) to find strokes in patients receiving carotid endarterectomy.

The "definite stroke" algorithm identified patients whose stroke could only have occurred during the thirty days following the surgery (n = 35). The "possible stroke" algorithm also included patients whose event could not be placed with certainty in relation to the operation (n = 161). In other words, the first method chose patients either with an ICD-9-CM code for a neurologic surgical complication during the index admission or with a code consistent with stroke on readmission within thirty days. The second selection technique included all patients identified in the first algorithm plus those with ICD-9-CM codes consistent with stroke during the index admission.

Based on these definitions, I calculated the proportion of patients who experienced the following outcomes within 30 days of surgery: death, death or definite post-operative stroke (the minimum estimate of the stroke plus death risk), and death or any possible post-operative stroke (the maximum risk of death plus stroke that can be ascertained from the discharge abstract). Patients suffering fatal strokes were counted only once in the combined stroke and death totals. Confidence intervals for these proportions were calculated according to the exact method.[79]

Independent Variables. Patients' age, sex and race were ascertained from the discharge records in the MEDPAR file. To identify important medical conditions of patients, diagnostic codes were examined from both the surgical (index) admission and from any admissions whose discharge date

fell within the 6 months preceding the date of the index surgical procedure, in the method previously described by Wennberg.[78] If an index admission diagnosis could reasonably be interpreted as a potential complication of the endarterectomy, a patient was coded as having that condition only if it was also present on an admission preceding the index hospitalization. The following conditions were evaluated as risk factors for adverse outcomes: coronary artery disease, valvular heart disease, congestive heart failure, stroke, pulmonary disease, renal disease, diabetes, and the presence of any hospital admission during the previous 6 months. The ICD-9-CM codes used to define these conditions are provided in Appendix C.

Hospital surgical volume was defined based on the number of index carotid endarterectomies performed by each hospital on the Medicare population during the 15 month study period. Institutional size was defined as a continuous variable based on the number of hospital beds. Hospital teaching status was defined as a continuous variable based on the number of housestaff in accredited residency programs per hospital bed.

Analysis. Multiple logistic regression was used to test the association between each of the three outcomes and the clinical and institutional predictors described above.[80] Of the clinical variables considered, only the presence of coronary artery disease was significantly associated with 30 day mortality at the .10 level after controlling for age, sex, and surgical volume. Both sex and coronary artery disease were included in the reported logistic

regression models. Alternative specifications of the model in which teaching status and hospital size were treated as both dichotomous and ordinal variables were examined. Regardless of the specification of the model, the results were similar to those presented below. Two-way interactions between surgical volume and age, and age and sex were examined and were not significant.

The binomial distribution was used to test the hypothesis that the observed number of deaths plus definite strokes at an individual hospital exceeded the number that would have been expected had the hospital's outcomes equalled those of the highest volume hospitals.

Results

Operative mortality. Operative mortality increased markedly with age (Table 2). Those over age 70 faced a progressively increased risk, with those over age 80 facing a more than four-fold increase in the adjusted odds of death compared to those ages 65 to 69.

Operative risk was also higher at hospitals performing few endarterectomies on the Medicare population (Table 3). Patients undergoing carotid endarterectomy in hospitals in each of the three lower volume groups faced an increased risk of death compared to those receiving surgery in hospitals performing more than 40 endarterectomies per year. The increased risk associated with low-volume surgery was consistent across all specifications of the model examined. When a dichotomous variable was substituted for the three levels of lower hospital volume in an otherwise identical model, the adjusted odds ratio for 30 day mortality at hospitals performing 40 or fewer endarterectomies per year compared to higher volume hospitals was 2.83 (95% CI 1.11, 7.19). When volume is treated as a continuous variable in the same model the conclusion is still statistically significant ($p = .03$), and remains so after controlling for teaching status and hospital size.

Risk of death or stroke. Because it was not possible to characterize the timing in relation to surgery of the majority of strokes recorded on the

discharge abstract, both a minimum and a maximum estimate of post-operative death plus stroke risk are presented in Tables 4 and 5. Regardless of the definition used, the risk of death or stroke increases significantly with age and at lower volume hospitals.

Individual hospital outcomes. All hospitals were identified where the number of observed deaths or definite strokes was greater than would have been expected ($p < .10$ by chi-square analysis), using as the standard of comparison the outcome rate in those hospitals performing more than 40 carotid endarterectomies per year (Table 6). Twenty-two of the 139 New England hospitals performing endarterectomy were found to have high complication rates compared to high volume hospitals. Only 7 New England hospitals performed more than 40 carotid endarterectomies per year on the Medicare population, while 50 hospitals performed 5 or fewer.

The complication rates of the 7 high volume hospitals all fall in the low range (Table 7). No institution in that group had a death plus definite stroke rate greater than the average for hospitals in any other range of volume.

Discussion

This study identifies two risk factors for complications from carotid endarterectomy. First, the results demonstrate a markedly elevated mortality risk with increasing age. Two thirds of the New England Medicare patients undergoing endarterectomy were over the age of 70 and faced an average three-fold increased risk of operative death compared to younger patients. The non-fatal stroke trend parallels the mortality findings. These results contrast with the work of other authors who have found no significant increase in operative mortality and morbidity in elderly patients undergoing carotid endarterectomy.[50,73,74]

Ouriel and colleagues retrospectively compared the outcomes of 470 carotid endarterectomies at their own institution.[73] Seventy seven of the cases were performed on patients older than 75 years of age. The distribution of surgical indications between the two groups was similar, although other clinical comorbidities were not considered. None of the elderly patients died post-operatively compared to two (0.5%) fatalities in the younger cohort. The aggregate stroke and death rates were 3.9% in the elderly and 3.6% in those 75 year of age and younger (difference not statistically significant). In contrast to these results, I found a case fatality rate of 3.6% in the 685 patients 75 years and older. Several differences in methodology may explain the variation in the two sets of mortality rates. First, Ouriel is not explicit in the length of the post-operative period studied

and he is likely to have used the index hospitalization as his observation period. I observed all patients for 30 days regardless of the site of convalescence. In addition, over 25% of the patients in Ouriel's series were operated on for "non-hemispheric symptoms," a dubious indication for carotid endarterectomy. It is unknown what percentage of the New England cohort received the procedure for non-focal complaints. The most important distinction between the two studies is that Ouriel's patients were all operated on at one hospital, and thus are not equivalent to the community-wide experience represented by the New England cohort.

Making use of 6000 endarterectomy patient records in the Cleveland Vascular Society registry, Plecha and co-workers also reported no significant elevation in the stroke and death rates of patients 75 years of age and older.[74] While they concluded that "carotid endarterectomy is tolerated well by patients at all age levels," their data suggest an alternative trend. The mortality rate was 1.5% in patients less than 75 years of age, 2.2% in those 75 to 79, and 2.7% in those patients 80 years and older (difference not statistically significant at the .05 level). It is interesting to note that the death rates for my New England cohort were 1.9%, 3.2%, and 4.7% in those same age ranges (see Table 2). While the pattern is the same, the mortality rate is consistently higher in the New England population. This variation can be explained by the differences in the two studies' surgeons and the accounting methods employed to calculate death rates. Unlike my study which includes all endarterectomies on patients 65 years of age and older,

Plecha draws only from the experiences of a regional specialty society that enumerates strict membership criteria and scrutinizes its participants results.[81] Consequently, only results from veteran and highly credentialed surgeons who are willing to let their colleagues review their outcomes appear in Plecha's report. Another reason for lower death rates in the Cleveland Vascular Society's registry is that they consider the post-operative period to last only as long as the index hospitalization, not a full 30 days. Furthermore, they identified cases by procedures, not by patients, so that persons receiving serial bilateral endarterectomies or re-operations were counted multiple times in their denominator. These methodologic differences all lead to lower reported mortality rates, partially obscuring the risk of the operation in elderly patients over an entire region.

Similar to Ouriel and to Plecha, Richardson and Main "found no tendency toward increased negative outcomes as a result of the patients' advancing age."[50] Their study made use of all 705 endarterectomies performed in 41 Kentucky hospitals over an 18 month period. They clearly reported their detection and follow-up techniques; however, they did not publish sufficient data for the above conclusion to be scrutinized.

A second conclusion of my research is the inverse relationship between institutional surgical volume and complication rates. Patients undergoing surgery at low-volume hospitals faced a three-fold increased risk of death compared to those receiving surgery at high-volume hospitals. On this issue, too, there is divergence from the conclusions of others.[50,71,72]

Kempczinski and colleagues compared hospital volume and outcomes in 16 Cincinnati hospitals, stratifying by annual volumes of less than 50, 50 to 100, and greater than 100 endarterectomies.[72] They found no significant difference in mortality or stroke morbidity among the groups. While the overall mortality rates are comparable in their study and mine (2.3% and 2.5%, respectively), my results identify a clear pattern of increased risk with diminishing surgical volume. Kempczinski and colleagues stratified at much larger volumes than I chose, and thus may have obscured differences at hospitals performing relatively few endarterectomies. The difference may also reflect a more uniform standard of care among the 16 Cincinnati hospitals than I found across 139 institutions distributed over six states.

Using their study of 41 Kentucky hospitals, Richardson and Main could "not establish a link between total hospital volume of [carotid endarterectomy] and/or vascular operations of other types and untoward outcomes."[50] Like their assertion for the link between age and outcome, they offer no data with which to evaluate this conclusion. Similarly, Hertzer reports that in the Cleveland Vascular Society registry data set "hospital size had no measurable effect on the mortality or stroke morbidity rate of carotid endarterectomy" without showing the figures to support his position.[71]

There are several limitations to my study's methods that must be recognized. One potential criticism is that the data used to identify strokes are imperfect. The clinical information found in Medicare files is gleaned from forms designed and submitted for billing purposes. The diagnosis and

procedure information is recorded on the discharge summary by medical personnel, and then is converted to ICD-9-CM codes by hospital abstractors. After passing through fiscal intermediaries, claims files are subsequently submitted to the HCFA where they are stored on computers in the MEDPAR file. Clinical details may be lost or misinterpreted in the collection or storage process. In addition, skeptics point out that there is clear financial incentive for hospitals to bias coding toward larger remunerations, especially since the implementation of diagnosis-related groups (DRGs) as the primary reimbursement mechanism for Medicare.[82] The accuracy of the clinical information has not been well studied, but there is evidence that biases in the reporting of comorbidities have emerged since the DRG system was inplemented in 1983.[83] Moreover, even if the data is gathered appropriately, the claims forms offer no means to grade the severity of clinical symptoms. For stroke victims, the degree of symptoms and functional status are important for evaluating outcome.

The difficulty of timing strokes due to limited information in the MEDPAR claims file poses a second problem with the study's methodology. As discussed above, based on the claims data it was not always possible to know whether a stroke was the indication for, or a complication of, the surgery. In an attempt to handle this ambiguity, two algorithms were developed to select a lower and upper limit of the number of possible post-operative strokes suffered. The true stroke rate falls between these two

values, but the exact value cannot be ascertained with the current method of data collection.

Two lines of evidence suggest that the actual risk is considerably higher than the 4.2% minimum estimate of death plus stroke risk presented here and may even be closer to the maximum estimate of 11.9%. First, a population-based sample of Medicare patients undergoing carotid endarterectomy in 1981 were found to have a combined death plus stroke risk of 9.8% based on review of hospital records.[65] Second, each of six recently reported case series that described the outcomes of carotid endarterectomy across multiple hospitals reported a ratio of non-fatal strokes to deaths of approximately two-to-one.[46-48,65,71,84] Applying this ratio to the data presented here would suggest a stroke plus death risk of 7.5% overall.

In order to address these coding and timing issues associated with post-operative stroke identification, I performed a pilot study of the accuracy of the claims data (see Appendix D). I compared strokes recognized by the claims data (using both algorithms) to strokes found by chart review in a sample of patients. The conservative algorithm was found to be 50% sensitive (confidence interval: 15% to 85%) and 96% specific (CI: 90% to 99%) for identifying complications. The liberal method, used to find all strokes that may have occurred post-operatively, was 88% sensitive (CI: 65% to 99%) and 80% specific (CI: 68% to 91%). Its positive predictive value was 41% (CI: 18% to 64%). The confidence intervals for these values are large.

This effort represents a preliminary study of small sample size that will need larger follow-up.

A similar examination of the validity of Medicare claims data has recently been undertaken on a much larger scale by Fisher.[85] He compared the data from the National DRG Validation Study with the results of chart reabstractions performed by reviewers from Health Data Institute. He was not specifically interested in the temporal relationship of diagnoses and procedures. For a similar, although not identical, definition of stroke by ICD-9-CM codes, the Medicare claims data were found to be 92% sensitive (CI: 88% to 95%), 97% specific (CI: 96% to 97%), and to have a positive predictive value of 71% (CI: 65% to 76%). Interestingly, only 90% (CI: 73% to 98%) of carotid endarterectomies were identified by the claims data.

Critics may also question the quality of the mortality figures. This information is collected by the Social Security Administration (SSA) for the purpose of controlling benefits paid by the federal government. A recent internal SSA study of the ascertainment of death found the reporting to be highly accurate. Prior to 1982, the agency used data that was evaluated to be 97% sensitive for finding deaths, when compared to state vital statistics (their "gold standard"). Since that time, the even more accurate data from the states' vital statistics has been encorporated into the SSA death files.[86]

The use of an independent data gatherer (i.e. the SSA) to find fatalities offers an advantage over all other studies of the complications of endarterectomy. While patients who have died after discharge but within

the post-operative period (defined herein as 30 days) may be lost in some studies, there is complete follow-up with this method. The same may be assumed about the completeness of follow-up for strokes after discharge, because all rehospitalizations are present in the MEDPAR file, regardless of whether readmissions are to the same institutions or to any other hospitals in New England.

A separate set of criticisms raised about the methodology relates to the study population. Like many other reports on the outcomes of endarterectomy surgery, the operative candidates here were not a uniform group with a single risk for stroke or death. While comorbidities were considered in the analysis, the indication for surgery in these patients could not be ascertained from the data set. The risk of surgical complications appears to be lowest in asymptomatic candidates, intermediate in those with TIAs, and greatest in patients with strokes in evolution or completed strokes.[23] In addition, some complications, especially cardiac events, may have been the consequence of another aspect of patient care. Some surgeons advocate prophylactic endarterectomy prior to coronary artery bypass grafting (CABG) in those patients with stenotic carotid arteries. In instances when both operations are performed during the same hospitalization cardiac events are more likely due to CABG than to endarterectomy. Thirty patients in this study cohort had both procedures performed during the index admission, and there were no deaths in the follow-up period.

Finally, some have argued that the diseases coded in discharge abstracts may not provide sufficient information to adequately control for severity of illness and comorbidity.[87] The technique employed to control for case mix identified coronary artery disease as the only medical comorbidity to act as an independent risk factor for death. This conclusion is consistent with the large amount of evidence that more patients die of coronary than carotid artery disease immediately after endarterectomy. The claims data allowed for only a dichotomous assessment of coronary artery disease (i.e. present versus absent), however, as opposed to more subtle characterizations of that condition such as the Goldman index.[88,89]

There may be differences in case mix between hospitals that perform many and few endarterectomies. Such a bias could potentially misrepresent the volume-outcome relationship in either direction. If high volume hospitals operate on more patients who have a low risk for stroke without surgery (more asymptomatic patients, for example) this could explain both their high endarterectomy volumes and their low complication rates. Also plausible, though, is the scenario that high volume hospitals serve as referral centers that receive more, not less, challenging cases. Furthermore, if the complication rates are not due to operative efficacy, the findings may indicate that high volume hospitals are better able to choose appropriate surgical candidates. Because comorbidities are imperfectly addressed by the claims data, questions remain on this issue.

While results from randomized controlled trials of the surgery would be preferable to all other means of data collection for assessing outcomes, that information is not currently available. The only completed trial was performed over twenty years ago,[35] and its results may no longer be valid because of improved surgical techniques and post-operative management. Several large randomized controlled trials--both for asymptomatic patients[90,91] and those with TIAs[92]--are ongoing, but most of their results will not be known until at least the middle of the 1990s. A preliminary report from the asymptomatic arm of the Veteran's Administration cooperative study revealed a 1.9% risk of death and a 2.4% risk of non-fatal stroke at thirty days, but no independent review or formal publication of these data has yet occurred.[93] In the interim, strong disagreement remains over which candidates, if any, are appropriate for surgery.

Even when the results of the current randomized controlled trials are known, uncertainty will remain. These studies will provide data on a best case scenario, but not on the spectrum of surgery that is presently available. All of these trials are being performed at major academic institutions, where surgical volumes are high, and thus outcomes are presumably better than average. Also, one of the trials (the ACAS study) requires that a surgeon perform a minimum number of endarterectomies before being allowed to operate on study patients, and that an institutional audit be performed if a center exceeds a threshold complication rate during the trial.[94]

Given the current uncertainty about the value of carotid endarterectomy, the importance of operative risk relative to the expected benefit of the procedure, and the wide variation in post-operative complication rates at individual hospitals, patients and their physicians should seek reliable data on the operative risk of death and stroke at the hospital where the operation is to be performed. These data are currently unavailable. One solution would be for individual hospitals to review their records and report their results. Such a monitoring program would be limited by the degree to which hospitals could ascertain post-discharge events and by concern about the potential conflict of interest for hospitals collecting and reporting the data.

This study suggests a practical alternative for reviewing and disseminating the data for the 70% of patients undergoing endarterectomy who are over the age of 65[34] and thus eligible for Medicare. Data in the claims files could be used to establish an ongoing monitoring program that would identify all patients undergoing endarterectomy and determine post-operative mortality. Chart reviews could be carried out to identify post-operative stroke rates and accurately classify patients' severity of illness and comorbidity. Accurate risk stratification, whether by age or clinical indications or both, would improve hospital comparisons and enhance individual clinical decision making. The effort required to obtain the necessary supplementary information through focused chart review would be far less than that required to establish a prospective data collection system.

The data could be made available to physicians and patients to provide them with the best available information with which to decide on the management of each unique case.[95]

An alternative approach for use of the claims data would rely on the liberal algorithm to identify all possible strokes in the Medicare population. This would act as a screen to find the small share of charts in need of chart review so that only the true post-operative strokes would be counted among the complications. Such a targeted approach to the review of in-hospital records would allow accurate identification of stroke victims without requiring a major chart review effort. The state of Kentucky made the only attempt at an organized monitoring system of chart review for the purpose of evaluating endarterectomy outcomes.[50] No screening mechanism such as the claims data was established, and the program was terminated after two years due to its financial burden.[96] By screening all endarterectomy cases for bad outcomes with the claims data, only a small fraction of their charts would need to be reviewed.

One limitation of a monitoring program would be that individual hospitals where few endarterectomies are performed could not be evaluated reliably. While some low-volume hospitals may have better results than others, the small number of cases available for review at these institutions makes it impossible to distinguish with certainty the few with excellent outcomes from those with worse than average performance. Where research supports a volume-outcome association, regionalization should lead to better

outcomes, as long as the hospitals to whom patients are referred have demonstrably lower complication rates. The difficulty in evaluating outcomes at low-volume hospitals obviously poses a problem for advocates of continued surgery at these institutions. From the patient's perspective, however, knowledge of the risk of complications at a specific institution is critical, especially for an elective procedure where the potential benefit depends upon a low complication rate. The Medicare claims files, supplemented as necessary with chart review, could provide an efficient mechanism for improving the information available to patients. Alternatively, the information gleaned from chart review could be used to direct appropriateness studies in the fashion proposed by Winslow and colleagues.[65]

If the HCFA adopts this method for surveillance of medical care, the agency could require the submission of appropriate pieces of clinical information for various medical conditions and surgical procedures. Such regulations would undoubtedly be expensive to implement, both because no standardized format currently exists and because health care providers already feel inundated with administrative requests. Furthermore, new biases would be introduced. While there is already suggestion that the DRG system of reimbursement has skewed coding to grant hospitals higher remunerations than before,[84] the systematized use of claims data for evaluating care would clearly introduce new incentives for doctors and hospitals to bias the reporting of their data.

Several areas of future research are needed to complete the course of the work reported here. First, the relationship of volume to complication rates in carotid endarterectomy needs further research. Using epidemiologic techniques, this study shows a correlation between outcome and volume. The logical next step is to understand the cause of this relationship. Part of this finding may be due to variation in case mix. If the finding is due to true differences in outcomes, however, the variation may be due to the surgeon's technical skill, institutional differences such as post-operative care, or both. One recent study looked at these two components of surgical outcomes for several different procedures.[97] It showed that for some operations the institution had more impact and for others the surgeon was the key influence on outcome. Carotid endarterectomy was not considered by that research team. As Medicare makes more data available for clinical review, Part B claims (physicians' billings) could be linked to the already created patient-specific files, and the impact of individual surgeons' volume could be evaluated.

Similar to the volume-outcome relationship, the correlation of age to complications needs to be examined. It is likely that age represents a proxy for various forms of physical decline or disease progression. While there is a relatively high risk from endarterectomy in the elderly, especially the very old, a large majority endure the surgery without complication. A more detailed examination of what conditions cause the elderly to suffer higher complication rates is needed in order to stratify this group, not only based

on age, but also by using pre-existing medical conditions. The claims data cannot perform this task, as it identifies comorbidities poorly. Only when these high-risk conditions are identified can endarterectomy be performed safely in those elderly who lack these poor prognostic signs.

A second research initiative is needed to further evaluate the use of claims data, not only as it relates to outcomes of carotid endarterectomy but also as it applies to other possible uses in health services research. A well designed study of the quality of the data regarding stroke coding and timing is needed. Currently only the pilot project examining the claims data is complete. Other researchers such as Fisher have begun work in this area.[85] As claims based research becomes a more common method for evaluating medical and surgical outcomes, a greater understanding of the data's accuracy and of the appropriate applications of the technique is necessary.

A third area of future investigation relates to more complete reporting of outcomes in the setting of carotid endarterectomy. The claims data can be used to gather information on surgical morbidities other than strokes. This would be especially useful in reviewing post-operative MIs, since this is a recognized complication of the operation with severe consequences. Using the data and methods reported in the body of this paper, I performed an initial examination of cardiac complications (including MI, unstable angina, and dysrhythmias). I found a 3.2% cardiac complication rate at 30 days (data not reported in the Results section), a finding consistent with the work

of others.[59,60] Additional work is required to carefully identify each of these complications and to examine their relationship to age and surgical volume.

At present, controversy exists over the role of carotid endarterectomy in the prevention of stroke. Given the uncertain benefit of the operation in reducing subsequent strokes, it is unreasonable to perform it in patients at high risk for severe complications. This study demonstrates significantly elevated risk in two settings--advanced patient age and low hospital endarterectomy volume. These correlations raise question about the appropriate candidates and settings for the operation, and future research is needed to clarify the causes of these risks. In addition, the claims data can potentially be used to create an on-going system of data collection and dissemination to inform providers and patients of the institution-specific risk.

Table 2

Death Within 30 Days of Carotid Endarterectomy
Risk and Adjusted Odds Ratio by Patient Age

Patient Age	Cases	Deaths	Risk (95% C.I.)	Adjusted Odds Ratio* (95% C.I.)
65-69	733	8	1.1% (0.5,2.1)	1.00
70-74	671	19	2.8% (1.7,4.4)	2.58 (1.12,5.95)
75-79	473	15	3.2% (1.8,5.2)	2.91 (1.22,6.95)
80 +	212	10	4.7% (2.3,8.5)	4.46 (1.73,11.50)
TOTAL	2089	52	2.5% (1.9,3.3)	----

*Derived from multiple logistic regression with age, sex, surgical volume, and presence or absence of coronary artery disease as covariables. The 65 to 69 year old group is the reference.

Table 3

Death Within 30 Days of Carotid Endarterectomy
Risk and Adjusted Odds Ratio by Procedure Volume

Hospital Volume*	Cases	Deaths	Risk (95% C.I.)	Adjusted Odds Ratio** (95% C.I.)
Over 40	457	5	1.1% (0.3,2.5)	1.00
21-40	561	15	2.7% (1.5,4.4)	2.63 (0.94,7.32)
6-20	913	27	3.0% (2.0,4.3)	2.90 (1.10,7.62)
5 or less	158	5	3.2% (1.0,7.2)	3.14 (0.89,11.06)
TOTAL	2089	52	2.5% (1.9,3.3)	----

---

* Volume defined as the number of carotid endarterectomies performed per year on the Medicare population at each hospital.

** Derived from multiple logistic regression with age, sex, surgical volume, and presence or absence of coronary artery disease as covariables. The over 40 operations category is the reference.

Table 4

Death or Stroke within 30 Days of Carotid Endarterectomy
Risk and Adjusted Odds Ratios (AOR) by Patient Age

	Death or Definite Stroke		Death or Possible Stroke	
Patient Age*	Risk (95% C.I.)	AOR** (95% C.I.)	Risk (95% C.I.)	AOR** (95% C.I.)
65-69	2.7% (1.7,4.2)	1.00	8.7% (6.8,11.0)	1.00
70-74	4.3% (2.9,6.2)	1.59 (0.89,2.84)	13.1% (10.7,15.9)	1.61 (1.15,2.27)
75-79	5.1% (3.3,7.5)	1.87 (1.02,3.44)	12.7% (9.8,16.0)	1.54 (1.06,2.25)
80 +	6.6% (3.7,10.8)	2.54 (1.25,5.14)	17.0% (12.2,22.7)	2.21 (1.42,3.45)
TOTAL	4.2% (3.3,5.1)	----	11.9% (10.5,13.3)	----

* See Table 2 for numbers of patients considered in each category.

** Derived from multiple logistic regression with age, sex, surgical volume, and presence or absence of coronary artery disease as covariables. The 65 to 69 year old group is the reference.

Table 5

Death or Stroke within 30 Days of Carotid Endarterectomy
Risk and Adjusted Odds Ratios (AOR) by Procedure Volume

	Death or Definite Stroke		Death or Possible Stroke	
Hospital Volume**	Risk (95% C.I.)	AOR* (95% C.I.)	Risk (95% C.I.)	AOR* (95% C.I.)
Over 40	2.0% (0.9,3.7)	1.00	9.2% (6.7,12.2)	1.00
21-40	4.6% (3.0,6.7)	2.52 (1.16,5.44)	10.9% (8.4,13.7)	1.19 (0.78,1.80)
6-20	4.7% (3.4,6.3)	2.55 (1.23,5.28)	13.0% (10.9,15.4)	1.46 (1.00,2.12)
5 or less	5.7% (2.6,10.5)	3.13 (1.22,8.07)	16.5% (11.0,23.2)	1.96 (1.15,3.32)
TOTAL	4.2% (3.3,5.1)	----	11.9% (10.5,13.3)	----

* Derived from multiple logistic regression with age, sex, surgical volume, and presence or absence of coronary artery disease as covariables. The first level of each category is the reference.

** Volume defined as the number of carotid endarterectomies performed per year on the Medicare population at each hospital. See Table 3 for the number of patients considered in each category.

Table 6

Number of Hospitals Identified as Exceeding Outcome Thresholds by Surgical Volume

Hospital Volume*	Number of Hospitals in Group	Hospitals Identified with Definite Stroke Plus Death Rates Significantly Above Expected ($p \leq .10$)**
1 to 5	50	6
6 to 20	65	10
21 to 40	17	6
Over 40	7	0
TOTAL	139	22

* Volume defined as the number of carotid endarterectomies performed per year on the Medicare population at each hospital.

** For each hospital, the expected proportion of definite strokes plus deaths is assumed to be .0197, the proportion that occurred in the high-volume hospitals. Given this proportion, the probability that a hospital would have at least as many strokes plus deaths as actually reported is computed. A hospital where this probability is .10 or less (using a chi-square test) is considered to have a significantly high rate. The number of definite strokes plus deaths is assumed to have a binomial distribution.

Table 7

Complication Rates of High Surgical Volume Hospitals

Hospital	Death (%)	Death or Definite Stroke (%)	Death or Possible Stroke (%)
A	0.0	0.0	9.4
B	0.0	0.0	13.0
C	0.0	3.1	6.2
D	1.0	1.0	6.1
E	1.5	4.6	16.9
F	1.9	1.9	5.8
G	3.4	3.4	8.5
RANGE	0.0 - 3.4	0.0 - 4.6	5.8 - 16.9

APPENDIX A

ICD-9-CM CODES USED TO IDENTIFY STROKES

I. Codes included in stroke identification, with headings for types of stroke code.

ICD-9-CM CODE	DEFINITION
1. Symptom of stroke	
342.0	Flaccid hemiplegia
342.1	Spastic hemiplegia
342.9	Hemiplegia, unspecified
344.3	Monoplegia of lower limb
344.4	Monoplegia of upper limb
344.5	Unspecified monoplegia
784.3	Aphasia
2. Pathologic definition of stroke	
434	Occlusion of cerebral arteries
434.0	Cerebral thrombosis
434.1	Cerebral embolism
434.9	Cerebral artery occlusion, unspecified
3. Acute cerebrovascular disease	
436	Acute, but ill-defined cerebrovascular disease
4. Late effects of cerebrovascular disease	
438	Late effects of cerebrovascular disease
5. Surgical complication	
997.0	Central nervous system complication of surgical or medical care

II. Codes considered and rejected for use in identification of strokes.

Quadriplegia, paraplegia, diplegia, paralysis (unspecified), anoxic brain damage, encephalopathy (unspecified), all cranial nerve disorders, retinal vascular occlusion, intracerebral hemorrhage, other unspecified intracranial hemorrhage, occlusion and stenosis of precerebral arteries, transient cerebral ischemia, other generalized ischemic cerebrovascular disease, coma, stupor, syncope, collapse, dizziness, abnormality of gait, lack of coordination, transient limb paralysis, disturbance of skin sensation, voice disturbance, other speech disturbance (including dysarthria, dysphasia, and slurred speech), other symbolic dysfunction (including alexia, agraphia, acalculia, agnosia, and apraxia).

APPENDIX B

DEFINITION OF POST-OPERATIVE STROKES

I. Definite Post-operative Strokes

TYPE OF STROKE CODE	CRITERIA
1. Symptom of stroke	Code must appear on post-index admission and may not appear on index or prior admission
2. Pathologic definition	Code must appear on post-index admission and may not appear on index or prior admission
3. Acute CV disease	Code must appear on post-index admission
4. Late effects of CV disease	Code must appear on post-index and may not appear on index or prior admission
5. Surgical complication	Code must appear on index or post-index admission

II. Possible Post-operative Strokes

TYPE OF STROKE CODE	CRITERIA
1. Symptom of stroke	Code must not appear prior to index admission
2. Pathologic definition	Code must not appear prior to index admission
3. Acute CV disease	Code may appear prior to index admission as long as it also appears on index or post-index admission

Notes:

1. The definitions of the "Types of Stroke Codes" are found in Appendix A.

2. In order to qualify as a stroke victim, a patient had to meet any one of the entries' criteria; only patients who met these criteria were defined as having had a post-operative stroke.

3. Patients who met the criteria for both possible and definite post-operative stroke were counted only among the definite post-operative stroke victims.

APPENDIX C

ICD-9-CM CODES USED TO DEFINE CLINICAL COVARIABLES*

Condition	ICD-CM-9 codes present on admissions occurring in previous 6 months	ICD-CM-9 codes on index admission**
Coronary artery disease	410, 411.1, 411.8, 412, 413, 414, 429.2	412, 413, 414, 429.2
Valvular disease	394 to 397, 421 to 422.9, 424	394 to 397, 421 to 422.9, 424
Congestive heart failure	402.01, 402.11, 402.91, 428, 429.3	none
Pulmonary disease	466, 480 to 486, 490 to 496	490 to 496
Renal disease	580 to 586	580 to 586, exclude 584
Diabetes	250 to 250.91	250 to 250.91, except 250.10, 250.20, 250.30

---

* Clinical condition was coded as present if the specified codes were recorded on index or preceding admission.

** Diagnostic codes that represent conditions that could have occurred as a complication of the endarterectomy are not used to create the clinical covariable.

APPENDIX D

A STUDY OF THE SENSITIVITY AND SPECIFICITY OF THE CODING OF STROKE IN THE MEDICARE CLAIMS DATA

Introduction

A small, unfunded study of the validity of the clinical information catalogued in the Medicare claims data was performed.

Methods

The medical records were requested for 101 patients who received carotid endarterectomy in one of 14 hospitals in New Hampshire or Vermont between April 1, 1984 and June 30, 1985. The sample chosen included all patients operated on in the two states who had a complication according to the Medicare claims data (n = 27). Of those patients whose outcomes were benign according to the claims data, all patients who were rehospitalized within thirty days were sampled (n = 21). The rest of the sample was drawn randomly from those patients without complication according to the claims data (see Table 1).

TABLE 1: CHART ACQUISITION

	complications by claims data (liberal method)	readmit w/in 30 d	neither	total
charts requested	27	21	53	101
charts received	17	10	38	65

The medical records department at each hospital was asked to photocopy the discharge abstract, discharge summary, physicians' and nurses' notes, operative report, laboratory reports, and reports of radiographic studies for identified patients during specified time intervals. Information was sought from the hospitalization for the first endartectomy ("index admission") plus all subsequent admissions to any New England hospital within 30 days of the index procedure.

Seven institutions responded to the initial inquiry or a follow-up request. The rest did not respond to repeated queries or refused to comply due to issues of patient confidentiality (although anonymity for both hospitals and patients was pledged). The primary responders were the four hospitals in New Hampshire with the largest Medicare caseloads in the state. Sixty five charts were collected. Six cases were disqualified from study because the medical record of a follow-up admission within 30 days of index operation was unavailable. One patient was excluded from the

study because the photocopied version provided for our review lacked the section of the chart containing physicians' notes.

A stroke was defined as any hemispheric event causing unilateral weakness, paralysis, or changes in sensation, aphasia of any type, or monocular blindness. Symptoms of vertebral-basilar strokes, including vertigo, ataxia and syncope, were not included in our definition of stroke because we we interested only in the manifestations of carotid artery disease. Symptoms that resolved in less than one week were considered to be transient ischemic attacks (TIAs) or reversible ischemic neurologic deficits (RINDs), and were not counted as strokes. Complications to vocal cords were considered to be the result of local damage to the recurrent laryngeal nerve, and were not counted as strokes. If a patient had neurologic impairment prior to surgery that was observed to be worse post-operatively, it was considered a new stroke. In order for any possible stroke symptom to identify a patient as having had a stroke, it had to be reported on two separate occasions in the physicians' and/or nurses' notes, and at least one time the note had to come from an MD. Deaths were recorded regardless of their cause.

The charts were reviewed without knowledge of the outcomes reported for each patient in the claims data.

Results

Of the 58 patients whose charts were reviewed, one never had an endartectomy. That patient received an intracranial-extracranial bypass operation. His results were not included in subsequent analyses. Seven of the patients suffered a post-operative stroke or died.

The information gained from chart review was used as a standard for comparison with the outcomes generated by the claims data. The sensitivity and specificity and positive predictive value of the Medicare claims data to report post-operative complications was computed using two different measures of poor outcomes: death plus definite strokes (conservative algorithm), and death plus all possible strokes (liberal algorithm). The two-by-two tables of these algorithms are provided below.

TABLE 2
2X2 TABLE EVALUATING CLAIMS DATA
FOR THE REPORTING OF STROKE OR DEATH
CONSERVATIVE ALGORHYTHM FOR STROKE

		CHART REVIEW +	CHART REVIEW -
CLAIMS DATA	+	4	2
	-	4	47

Sensitivity = .50 (CI: .15, .85)
Specificity = .96 (CI: .90, .99)
Positive predictive value = .67 (CI: .29, .99)

TABLE 3
2X2 TABLE EVALUATING CLAIMS DATA
FOR THE REPORTING OF STROKE OR DEATH
LIBERAL ALGORHYTHM FOR STROKE

		CHART REVIEW	
		+	-
CLAIMS DATA	+	7	10
	-	1	39

Sensitivity = .88 (CI: .65, .99)
Specificity = .80 (CI: .68, .91)
Positive predictive value = .41 (CI: .18, .64)

Comment

This small study demonstrates that the claims data can be used to report outcomes of stroke with a specificity of at least 90%. A second finding of interest is that by using the more liberal definition of stroke, it appears that the claims data can be used to screen endarterectomy surgery for bad outcomes. The sensitivity of the claims data, when the broader definition of stroke is used, was 88%. Follow-up chart review is necessary

to determine which of these patients had surgical complications. Nonetheless, only a small subset of the total population receiving endarterectomy would need in-depth review of their medical records in order to monitor complications of the surgery.

This was a pilot study to check the validity of the reporting of stroke and death in the Medicare claims data. Because there were few endpoints in this sample, the confidence interval, especially surrounding sensitivity, are large. As a result, conclusions cannot be reached with certainty, and a larger study is needed.

Acknowledgements

While this thesis is presented as my own work, it was more accurately a team effort. I am deeply endebted to my co-captains, David Malenka and Elliott Fisher, for giving me direction, support, and much technical assistance. They have been wonderful mentors and great friends. Other members were also instrumental in vital aspects of the project. Jack Wennberg provided access to the claims data and to his office, and served in a paternal role. Tom Bubolz took the raw data files from the Health Care Financing Administration and made them interpretable. Rick Whalley assisted with statistical analyses.

David Ransohoff provided critical comments throughout the duration of my research. His guidance was most appreciated. Walter Kernan, my departmental reviewer, made several valuable suggestions. Ellen Fox helped me transform a crude text into a readable document; I love everything that she does. Finally, I am grateful to members of my family for offering never-ending support and advice, even when they cannot figure out what it is that I am up to.

References

1. Garraway, WM, et.al.: The declining incidence of stroke. New England Journal of Medicine 1979; 300: 449-52.

2. Grotta, JC: Current medical and surgical therapy for cerebrovascular disease. New England Journal of Medicine 1987; 317: 1505-16.

3. Kuller, LH, Sutton, KC: Carotid artery bruit: is it safe and effective to auscultate the neck? Stroke 1984; 15: 944-47.

4. Dyken, ML, et.al.: Risk factors in stroke: a statement for physicians by the subcommittee on risk factors and stroke of the stroke council. Stroke 1984; 15: 1105-11.

5. Hodgdon, TA, Kopstein, AN: Health care expenditures for major diseases in 1980. Health Care Financial Review 1984; 5: 1-12.

6. Mohr, JP: The Harvard Cooperative Stroke Registry: A prospective registry. Neurology 1978; 28: 754-62.

7. Hypertension Detection and Follow-up Program Cooperative Detection Group: Five-year findings of the hypertension detection and follow-up program: III. Reduction in stroke incidence among persons with high blood pressure. JAMA 1982; 247: 633-38.

8. Whisnant, JP: The decline of stroke. Stroke 1984; 15: 160-68.

9. Grotta, JC: Current medical and surgical therapy for cerebrovascular disease. New England Journal of Medicine 1987; 317: 1505-16.

10. Abbott, RD, et.al.: Risk of stroke in male cigarette smokers. New England Journal of Medicine 1986; 315: 717-20.

11. Tell, GS, et.al.: Cigarette smoking cessation and extracranial carotid atherosclerosis. JAMA 1989; 261: 1178-80.

12. Gill, JS, et.al.: Stroke and alcohol consumption. New England Journal of Medicine 1986; 315: 1041-46.

13. Khaw, K-T, Barrett-Conner, E: Dietary potassium and stroke-associated mortality: a 12-year prospective population study. New England Journal of Medicine 1987; 316: 235-40.

14. Heyman, A, et.al.: Risk of stroke in asymptomatic persons with cervical arterial bruits, a population study in Evans County, Georgia. New England Journal of Medicine 1980; 302: 838-41.

15. Wolf, PA, et.al.: Asymptomatic carotid bruit and risk of stroke, the Framingham study. JAMA 1981; 245: 1442-45.

16. Roederer, GO, et.al.: The natural history of carotid arterial disease in asymptomatic patients with cervical bruit. Stroke 1984; 15: 605-13.

17. Whisnant, JP, et.al.: Transient cerebral ischemic attacks in a community, Rochester, Minnesota, 1955 through 1969, Mayo Clinic Proceedings 1973; 48: 194-98.

18. Simonsen, N, et.al.: Long-term prognosis after transient ischemic attacks. Acta Neurologica Scandinavia 1981; 63: 156-68.

19. Fields, WS, Lemak, NA: Joint study of extracranial arterial occlusion: IX. Transient ischemic attacks in the carotid territory. JAMA 1976; 235: 2608-10.

20. Fields, WS, et.al.: Controlled trial of aspirin in cerebral ischemia. Stroke 1977; 8: 301-15.

21. Canadial Cooperative Study Group: A randomized trial of aspirin and sulfinpyrazone in threatened stroke. New England Journal of Medicine 1978; 299: 53-59.

22. Cartlidge, NE, et.al.: Carotid and vertebro-basilar transient cerebral ischemic attacks, a community study, Rochester, Minnesota. Mayo Clinic Proceedings 1977; 52: 117-20.

23. Committee on Health Issues, American Neurological Society: Does carotid endarterectomy decrease stroke and death in patients with transient ischemic attacks? Annals of Neurology 1987; 22: 72-76.

24. Podore, PC, et.al.: Asymptomatic contralateral carotid artery stenosis: a five-year follow-up study following carotid endarterectomy. Surgery 1980; 88: 748-52.

25. UK-TIA Study Group: United Kingdom transient ischemic attack (UK-TIA) aspirin trial: interim results. British Medical Journal 1988; 296: 316-20.

26. Sorensen, PS, et.al.: Acetylsalicylic acid in the prevention of stroke in patients with reversible cerebral ischemic attacks: a Danish cooperative study. Stroke 1983; 14: 15-23.

27. Bousser, MG, et.al.: "AICLA" controlled trial of aspirin and dipyridamole in the secondary proevention of athero-thrombotic cerebral ischemia. Stroke 1983; 14: 5-14.

28. Levine, M, Hirsh, J: Hemorrhagic complications of long-term anti-coagulant therapy for ischemic cerebral vascular disease. Stroke 1986; 17 111-16.

29. Kase CS, et.al.: Anticoagulant-related intracerebral hemorrhage. Neurology 1985; 35: 943-48.

30. Petty, G, et.al.: Complications of long term anticoagulation. Annals of Neurology 1986; 20: 156.

31. The EC/IC Bypass Study Group: Failure of extracranial-intracranial arterial bypass to reduce the risk of ischemic stroke: results of an international randomized trial. New England Journal of Medicine 1985; 313: 1191-200.

32. Dyken, ML: Carotid endarterectomy studies: a glimmering of science. Stroke 1986; 17: 355-58.

33. Dyken, ML, Pokras, R: The performance of endarterectomy for disease of the extracranial arteries of the head. Stroke 1984; 15: 948-50.

34. National Center for Health Statistics: Detailed diagnoses and surgical procedures for patients discharged from short-stay hospitals. Government Printing Office, Washington, D.C., 1985-1988. Note that this is an annual publication, and data were taken for years 1983 to 1987 from the issues printed in 1985 to 1988.

35. Fields, WS, et.al.: Joint study of extracranial arterial occlusion. JAMA 1970; 211: 1993-2002.

36. Shaw, DA, et.al.: Carotid endarterectomy in patients with transient cerebral ischemia. Journal of Neurologic Sciences 1984; 64: 45-53.

37. Fode, NC, et.al.: Multicenter retrospective review of results and complications of carotid endarterectomy in 1981. Stroke 1986; 17: 370-76.

38. Zurbruegg, HR, et.al.: Morbidity and mortality of carotid endarterectomy, a literature review of the results reported in the last ten years. Acta Neurochirugica 1987; 84: 3-12.

39. Warlow, C: Carotid endarterectomy: Does it work? Stroke 1984; 15: 1068-76.

40. Shinar, D, et.al.: Interobserver variability on the assessment of neurologic history and examination in the stroke data bank. Archives of Neurology 1985; 42: 557-65.

41. Sisk, C, et.al.: Discrepancies in recorded results from duplicate neurological history and examination in patients studied for prognosis in cerebral disease. Stroke 1970; 1: 14-18.

42. Thompson, JE: Carotid endarterectomy, 1982--the state of the art. British Journal of Surgery 1983; 70: 371-76.

43. Javid, H, et.al.: Seventeen-year experience with routine shunting in carotid artery surgery. World Journal of Surgery 1979; 3: 167-77.

44. Stanford, JR, et.al.: Prevention of stroke by carotid endarterectomy. Surgery 1978; 83: 259-63.

45. Ennix, CL, et.al. Improved results of carotid endarterectomy in patients with symptomatic coronary artery disease: an analysis of 1546 consecutive carotid operations. Stroke 1979; 10: 122-25.

46. Fode, NC, et.al.: Multicenter retrospective review of results and complications of carotid endarterectomy in 1981. Stroke 1986; 17: 370-76.

47. Toronto Cerebrovascular Study Group: Risks of carotid endarterectomy. Stroke 1986; 17:848-52.

48. Brott, TG, et.al.: Changing patterns in the practice of carotid endarterectomy in a large metropolitan area. JAMA 1986; 255: 2609-12.

49. Roblin, DW, et.al.: "The predictive value of claims data for analysis of adverse outcomes of carotid endarterectomy." Presented at the American Medical Review Research Center Second Annual Research Symposium, 1987.

50. Richardson, JD, Main, KA: Carotid endarterectomy in the elderly population: a statewide experience. Journal of Vascular Surgery 1989; 9: 65-73.

51. Hertzer, NR, et.al.: A prospective study of the incidence of injury to the cranial nerves during carotid endarterectomy. Surgery, Gynecology and Obstetrics 1980; 151: 781-84.

52. Liapis, CD, et.al.: Motor speech malfunction following carotid endarterectomy. Surgery 1981; 89: 56-59.

53. Verta, MJ, et.al.: Cranial nerve injury during carotid endarterectomy. Annals of Surgery 1977; 185: 193-95.

54. Glover, JL, et.al.: Restenosis following carotid endarterectomy: evaluation by duplex ultrsonography. Archives of Surgery 1985; 120: 678-84.

55. Kremen JE, et.al.: Restenosis or occlusion after carotid endarterectomy: a survey with occular plethysmography. Archives of Surgery 1979; 114: 608-10.

56. Stoney, RJ, String, ST: Recurrent carotid stenosis. Surgery 1976; 80: 705-10.

57. Shumway, SJ, et.al.: Recurrent carotid stenosis: incidence and risk factors. The American Surgeon 1987; 53: 61-65.

58. Piepgras, DG, et.al.: Recurrent carotid stenosis: results and complications of 57 operations. Annals of Surgery 1986; 203: 205-13.

59. Riles, TS, et.al.: Myocardial Infarction following carotid endarterectomy: a review of 683 operations. Surgery 1979; 85: 249-52.

60. O'Donnell, TF, et.al.: The impact of coronary artery disease on carotid endarterectomy. Annals of Surgery 1983; 198: 705-12.

61. Chassin, MR, Brook, RH, et.al.: Variations in the use of medical and surgical services by the medicare population. New England Journal of Medicine 1986; 314: 285-90.

62. UK-TIA Study Group: Variations in the use of angiography and carotid endarterectomy by neurologists in the UK-TIA aspirin trial. British Medical Journal 1983; 286: 514-17.

63. Wennberg, JE, et.al.: Are hospital services rationed in New Haven or over-utilized in Boston? Lancet 1987; 1: 1185-88.

64. Jonas, S, Hass, WK: An approach to the maximal acceptable stroke complication rate after surgery for transient cerebral ischemia (TIA). Stroke 1979; 10: 104.

65. Winslow, CM, et.al.: The appropriateness of carotid endarterectomy. New England Journal of Medicine 1988; 318: 721-27.

66. Matchar, DB, Pauker SG: Endarterectomy in carotid artery disease: a decision analysis. JAMA 1987; 258: 793-98.

67. Committee on Health Issues, American Neurological Society: Does carotid endarterectomy decrease stroke and death in patients with transient ischemic attacks? Annals of Neurology 1987; 22: 72-76.

68. Whisnant, JP, et.al.: Carotid endarterectomy for unilateral carotid system transient cerebral ischemia. Mayo Clinic Proceedings 1983; 58: 171-75.

69. Chambers, BR, Norris, JW: The case against surgery for asymptomatic carotid stenosis. Stroke 1984; 15: 964-67.

70. Luft, HS, et.al.: Should operations be regionalized? The empirical relation between surgical volume and mortality. New England Journal of Medicine 1979; 301:1364-69.

71. Hertzer, NR, et.al.: The risk of vascular surgery in a metropolitan community. Journal of Vascular Surgery 1984; 1: 13-20.

72. Kempczinski, RF, Brott, TG, Labutta, RJ: The influence of surgical specialty and caseload on the results of carotid endarterectomy. Journal of Vascular Surgery 1986; 3: 911-16.

73. Ouriel, K, et.al.: Carotid endarterectomy in the elderly patient. Surgery, Gynecology, and Obstetrics 1986; 162: 334-36.

74. Plecha, FR, et.al.: The early results of vascular surgery in patients 75 years of age and older: an analysis of 3259 cases. Journal of Vascular Surgery 1985; 2: 769-74.

75. Rosenthal, D, et.al.: Carotid endarterectomy in the octagenarian: is it appropriate? Journal of Vascular Surgery 1986; 3: 782-787.

76. Roper, WL, et.al.: Effectiveness in health care: an initiative to evaluate and improve medical practice. New England Journal of Medicine 1988; 319: 1197-1202.

77. DHHS Publication No. (PHS) 80-1260, US Department of HHS, vol. 1-3.

78. Wennberg, JE, et.al.: Use of claims data systems to evaluate health care outcomes: mortality and reoperation following prostatectomy. JAMA 1987; 257: 933-36.

79. Conover, WJ: Practical nonparametric statistics. New York, John Wiley & Sons Inc. 1971.

80. SAS Institute Inc.: SAS user's guide: statistics, version 5 edition. Cary, North Carolina. SAS Institute Inc. 1985.

81. Avellone, JC, et.al.: A regional specialty society as a model to monitor surgical care. JAMA 1978; 240: 2177-80.

82. Cohen, BB, et.al.: How will diagnosis-related groups affect epidemiologic research? American Journal of Epidemiology 1987; 126: 1-9.

83. Hsai, DC, et.al.: Accuracy of diagnostic coding for medicare patients under the prospective-payment system. New England Journal of Medicine 1988; 318: 352-55.

84. Kirshner, DL, et.al.: Risk factors in a community experience with carotid endarterectomy. Journal of Vascular Surgery 1989; 10: 178-86.

85. Fisher, ES: Personal communication, January 1990.

86. Office of Program and Integrity Reviews: Review of the Health Care Financing Administration Death Match (1001) and the National Death Match (1012). Social Security Administration, US Government. 1988.

87. Jencks, SF, et.al.: Assessing hospital-associated deaths from discharge data: the role of length of stay and comorbidities. JAMA 1988; 260: 2240-46.

88. Goldman, L, et.al.: Multifactorial index of cardiac risk in noncardiac surgical procedures. New England Journal of Medicine 1977; 297: 845-50.

89. Raby, KE, et.al.: Correlation between preoperative ischemia and major cardiac events after peripheral vascular surgery. New England Journal of Medicine 1989; 321: 1296-1300.

90. Role of carotid endarterectomy in asymptomatic carotid stenosis: a Veterans Administration cooperative study. Stroke 1986; 17: 534-39.

91. Mayo Asymptomatic Carotid Endarterectomy Study Group: Effectiveness of carotid endartectomy for asymptomatic carotid stenosis: design of a clinical trial. Mayo Clinic Proceedings 1989; 64: 897-904.

92. Barnett, HJ, Peerless, SJ: Proposed carotid endarterectomy study. Grant proposal (approved); 1986.

93. Towne, JB, et.al.: First phase report of cooperative VA asymptomatic carotid stenosis study--operative morbidity and mortality. The Society for Vascular Surgery, 43rd annual meeting. June 20, 1989.

94. Meier, GH: Personal communication, March 1989.

95. Luft, HS, Hunt, SS: Evaluating individual hospital quality through outcome statistics. JAMA 1986; 255: 2780-84.

96. Richardson, JD: Personal communication, September 1989.

97. Hannan, EL, et.al.: Investigation of the relationship between volume and mortality for surgical procedures performed in New York state hospitals. JAMA 1989; 262: 503-10.