LESS IS MORE

Geographic Variation in Carotid Revascularization Among Medicare Beneficiaries, 2003-2006

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Background: Little is known about patterns in the use of carotid revascularization since a 2004 Medicare national coverage decision supporting carotid artery stenting. We examined geographic variation in and predictors of carotid endarterectomy and carotid stenting.

Methods: Analysis of claims from the Centers for Medicare & Medicaid Services from January 1, 2003, through December 31, 2006. Patients were 65 years or older and had undergone carotid endarterectomy or carotid stenting. The main outcome measures were annual age-adjusted rates of carotid endarterectomy and carotid stenting, factors associated with the use of carotid revascularization, and mortality rate at 30 days and 1 year.

Results: The rate of endarterectomy decreased from 3.2 per 1000 person-years in 2003 to 2.6 per 1000 person-years in 2006. After adjustment for demographic and clinical characteristics, there was significant geographic variation in the odds of carotid revascularization, with the East North Central region having the greatest odds of endarterectomy (odds ratio, 1.60; 95% confidence interval, 1.55-1.65) and stenting (1.61; 1.46-1.78) compared with New England. Prior endarterectomy (odds ratio, 3.06; 95% confidence interval, 2.65-3.53) and coronary artery disease (2.12; 2.03-2.21) were strong predictors of carotid stenting. In 2005, mortality was 1.2% at 30 days and 6.8% at 1 year for endarterectomy and 2.3% at 30 days and 10.3% at 1 year for stenting.

Conclusions: Significant geographic variation exists for carotid endarterectomy and carotid stenting. Prior endarterectomy and coronary disease were associated with greater odds of carotid stenting.

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C A R O T I D E N D A R T E R E C T O M Y has been the recommended treatment for patients with extracranial carotid artery disease since the publication of several randomized studies1-5 in the 1990s comparing carotid endarterectomy with medical therapy. Trials in symptomatic and asymptomatic patients were stopped early because of the observed benefit of carotid endarterectomy.6 Interim results of 1 trial prompted a National Institutes of Health alert to physicians in 1991 that highlighted the benefit of carotid endarterectomy for some patients with recent transient ischemic attack or stroke when performed at centers with low rates of perioperative complications.7 In the years that followed, the use of carotid endarterectomy increased in the United States8 but varied considerably by geographic region.8-10 Among common surgical procedures, including procedures without a robust evidence base, carotid endarterectomy had some of the greatest geographic variation.8 Moreover, previous studies11,12 have found that 30-day mortality rates associated with carotid endarterectomy in the Medicare population are higher than rates reported in clinical trials, although the risk of mortality is lower at high-volume centers than at low-volume centers.

See Invited Commentary at end of article

With the recent development of embolic protection devices, several randomized trials have compared carotid endarterectomy with percutaneous carotid artery stenting in patients with carotid artery disease and have had mixed results regarding myocardial infarction, stroke, and death.13,14 Carotid stenting has been proposed as a therapeutic option for patients at high risk for surgical revascularization.15 On October 12, 2004, the US Centers for Medicare & Medicaid Services (CMS) issued a national coverage decision supporting the use of Food and Drug Administration–approved carotid artery stents with embolic protection devices for symptomatic patients at high surgical risk
or in the context of a clinical trial. In light of that decision and its potential influence on the use of carotid revascularization, we examined geographic variation in and predictors of carotid endarterectomy and carotid stenting among Medicare beneficiaries in the United States aged 65 and older (hereafter referred to as elderly beneficiaries).

METHODS

DATA SOURCES

We obtained all inpatient, outpatient, and carrier claim files from CMS for all Medicare beneficiaries who underwent carotid endarterectomy or carotid stenting from January 1, 2003, through December 31, 2006. We also obtained all claims for all beneficiaries who underwent carotid endarterectomy or carotid stenting from January 1, 2003, through December 31, 2006. We used the self-reported race data with regard to clinical indications for carotid revascularization. Because detailed data with regard to clinical indications for carotid revascularization are not available in claims data, we used prior angiography (invasive or noninvasive) as a proxy for potential eligibility for revascularization. We limited the cohort to patients with 12 months of Medicare eligibility before the index date. We used logistic regression models to assess the independent effects of age, sex, race, US Census region, comorbid conditions, and index year on the use of carotid endarterectomy or carotid stenting. We used SAS statistical software, version 9.2 (SAS Institute, Cary, North Carolina), for all analyses.

CAROTID REvascularization and Diagnostic Imaging

We identified patients who underwent carotid endarterectomy by searching carrier claims from January 1, 2003, through December 31, 2006, for evidence of carotid endarterectomy (HCPCS code 35301). The HCPCS codes specific to carotid stenting were assigned in 2004 and first appeared in the Medicare claims data in 2005. Therefore, we searched carrier claims from January 1, 2005, through December 31, 2006, for evidence of carotid stenting (HCPCS codes 37215 and 37216). We used the Medicare reimbursement codes assigned in 2004 and 2005 and the Medicare claims data in 2005. Therefore, we searched carrier claims from January 1, 2005, through December 31, 2006, for evidence of carotid stenting (HCPCS codes 37215 and 37216). We retained the claim-through date from each carrier claim as the carotid revascularization date. We searched all claims from the 365 days before the revascularization date for carotid ultrasonography (HCPCS codes 93873, 93880, and 93882), carotid MRA (codes 70547, 70548, and 70549), and carotid x-ray angiography (codes 70498, 75660, 75662, 75665, 75671, 75676, and 75680).

PATIENT CHARACTERISTICS

Patient demographic characteristics included age, sex, race, and state of residence. In this analysis, we used the self-reported race category of black and combined all other categories as other. We used state of residence to group beneficiaries into 9 US Census regions. We also assigned each beneficiary to 1 of 306 hospital regions according to zip code of residence. We also assigned each beneficiary to 1 of 306 hospital regions according to zip code of residence.

MORTALITY

We summarized all-cause mortality at 30 days and 1 year for beneficiaries who underwent carotid endarterectomy or carotid stenting in 2004 and 2005, the first full year in which carotid stenting was covered by Medicare. Beneficiaries who underwent carotid endarterectomy and carotid stenting during the year were included in both groups. Beneficiaries who had undergone multiple carotid endarterectomies or carotid stenting procedures during the year were followed up from the first observed procedure.

STATISTICAL ANALYSIS

We present categorical variables as frequencies with percentages. We used Kaplan-Meier methods to calculate the unadjusted 30-day and 1-year mortality rates. Using the direct standardization method, we calculated the annual age-adjusted rates of carotid endarterectomy and carotid stenting overall and by HRR. We calculated the annual rates of carotid endarterectomy and the rates for January 1, 2003, through December 31, 2004, and the rates for January 1, 2005, through December 31, 2006. We calculated the annual rates of carotid stenting for 2005 and 2006 only, because the HCPCS codes specific to carotid stenting were assigned late in 2004 after the CMS national coverage decision. We calculated the ratio of the intervention rates in each HRR to the national rates and mapped these ratios. We suppressed the results for HRRs with 10 or fewer revascularization procedures to minimize the effect of unreliable estimates.

In addition to calculating the rates of carotid revascularization, we calculated the rates of carotid imaging performed before carotid revascularization. For interventions performed in 2005, we identified the carotid imaging procedures performed during the 365 days before the carotid revascularization. For example, for patients who underwent 2 carotid ultrasonography examinations and a carotid x-ray angiography before a carotid stenting procedure, we describe the pattern as “ultrasonography and x-ray angiography.” For each patient, we defined the first MRA or x-ray angiography performed from January 1, 2004, through December 31, 2006, as the index event and followed up the patient for 1 year to identify the use of carotid revascularization. Because detailed data with regard to clinical indications for carotid revascularization are not available in claims data, we used prior angiography (invasive or noninvasive) as a proxy for potential eligibility for revascularization. We limited the cohort to patients with 12 months of Medicare eligibility before the index date. We used logistic regression models to assess the independent effects of age, sex, race, US Census region, comorbid conditions, and index year on the use of carotid endarterectomy or carotid stenting. We used SAS statistical software, version 9.2 (SAS Institute, Cary, North Carolina), for all analyses.
There were almost 30 million Medicare beneficiaries 65 years or older in each year from 2003 through 2006. **Table 1** gives the demographic characteristics and regional distribution of all Medicare beneficiaries in 2005 and the demographic characteristics, clinical characteristics, and previous diagnostic imaging test results of beneficiaries who underwent carotid endarterectomy or carotid stenting from January 1, 2005, through December 31, 2005. The distribution of study variables was similar in each year of the study period (data not shown).

A total of 66,698 eligible beneficiaries underwent carotid endarterectomy and 7,357 underwent carotid stenting in 2005. Among beneficiaries who underwent carotid endarterectomy, 56.1% were 75 years or older, 56.3% were men, and 3.4% were black. More than two-thirds of the beneficiaries had a prior diagnosis of coronary artery disease, 36.9% had a prior diagnosis of peripheral vascular disease, and 47.7% had a prior diagnosis of cerebrovascular disease. Carotid endarterectomy was most
In general, however, there was no clear relationship between the use of carotid stenting and that of carotid endarterectomy by HRR (data not shown).

**PREDICTORS OF CAROTID REVASCULARIZATION**

Table 3 gives the results of the models predicting the use of carotid endarterectomy and carotid stenting from 2004 through 2006 within 1 year of the first MRA or x-ray angiography. Carotid endarterectomy was performed more often in men (odds ratio [OR], 1.63; 95% confidence interval [CI], 1.61-1.65) and patients with peripheral vascular disease (1.37; 1.35-1.39). The procedure was more likely to be used in the East North Central region (1.60; 1.55-1.65) and the West North Central region (1.73; 1.67-1.80) compared with New England.

Carotid stenting was performed more often in men (OR, 1.62; 95% CI, 1.56-1.68), patients with peripheral vascular disease (1.58; 1.52-1.64), patients with coronary artery disease (2.12; 2.03-2.21), and patients who had undergone a previous carotid endarterectomy (3.06; 2.65-3.53). Carotid stenting was also more likely to occur in the Pacific region (1.65; 1.48-1.84) and the East North Central region (1.61; 1.46-1.78) compared with New England.

**MORTALITY**

Among patients who underwent carotid endarterectomy in 2004, 1029 (1.3%) died within 30 days of the index procedure and 5492 (7.0%) died within 1 year. In 2005, 845 (1.2%) died within 30 days of the index procedure and 4766 (6.8%) died within 1 year. Among patients who underwent carotid stenting, 178 (2.3%) died within 30 days of the index procedure and 803 (10.3%) died within 1 year.

In this retrospective cohort study of elderly Medicare beneficiaries, we found substantial geographic variation in the use of carotid endarterectomy and carotid stenting. The New England, Mountain, and Pacific regions tended to have the lowest rates of these procedures, whereas the East South Central, West South Central, East North Central, and West North Central regions tended to have higher rates of revascularization. There was a nearly 9-fold difference between the highest rate and lowest rate of carotid endarterectomy across HRRs in 2003 and 2004 and a 7-fold difference in 2005 and 2006. Across HRRs, the
rates of carotid stenting ranged from 0.07 to 2.73 per 1000 person-years. In general, there was no clear relationship between rates of carotid endarterectomy and rates of carotid stenting by HRR, and overall rates of carotid revascularization did not increase during the study period. Previous studies have found geographic variation in carotid endarterectomy, and a recent analysis reported regional variation in carotid stenting.

**Figure.** Hospital referral region (HRR) rates of carotid endarterectomy and carotid stenting. A, Ratio of rate of carotid endarterectomy by HRR to US national average, 2005-2006. B, Ratio of rate of carotid stenting by HRR to US national average, 2005-2006.
We also found considerable variation in the use of diagnostic imaging before carotid revascularization. Most patients who underwent carotid stenting had previously undergone ultrasonography and x-ray angiography; almost one-fifth underwent ultrasonography, MRA, and x-ray angiography; and more than 10% underwent ultrasonography alone. Ultrasonography and MRA preceded carotid endarterectomy in more than one-quarter of the patients, and ultrasonography and x-ray angiography preceded carotid endarterectomy in approximately one-third of the patients. In 26.8% of patients who underwent carotid endarterectomy, only ultrasonography had been performed.

Reliance on ultrasonography alone before carotid endarterectomy is controversial. In a comparison of neurovascular imaging modalities before carotid endarterectomy, ultrasonography alone misclassified 28% of patients.28 Yet, some have suggested that ultrasonography is sufficient for preprocedural imaging.27 In a survey of surgeons in Canada, 4 of 37 neurosurgeons (10%) and 42 of 91 vascular surgeons (46%) identified duplex ultrasonography alone as the imaging modality of choice before carotid endarterectomy.28 Our findings highlight the need for consensus regarding diagnostic imaging criteria for the identification and management of carotid artery disease.

We also found that the rate of carotid endarterectomy decreased slightly during the study period from 3.2 to 1000 person-years in 2003 to 2.6 per 1000 person-years in 2006. In the year immediately after the CMS national coverage decision supporting the use of carotid stenting,23 the rate of carotid stenting was 0.4 per 1000 person-years. These findings are generally consistent with a recent study29 that reported an endarterectomy rate of 2.7 per 1000 Medicare beneficiaries and a carotid artery stenting rate of 0.6 per 1000 beneficiaries. Whereas we relied on only those procedure codes specific to carotid artery stenting, Goodney and colleagues25 used a slightly expanded algorithm to identify carotid artery stenting. The coding algorithm likely explains the slight difference in observed rates.

The low observed rate of carotid stenting is likely related to the fact that the CMS national coverage decision for carotid stenting was limited to patients at high surgical risk. The overall rate of revascularization did not increase, even with the introduction of a new therapeutic option for patients with carotid artery disease, because the rate of carotid endarterectomy decreased. This pattern of carotid revascularization will require additional study as physicians become more familiar with carotid stenting.

To explore variations in carotid revascularization, we used regression models to identify factors associated with the use of carotid endarterectomy and carotid stenting. Male sex and prior diagnosis of peripheral vascular disease were associated with greater odds of carotid endarterectomy and carotid stenting. However, patients undergoing carotid stenting were more likely to have a prior diagnosis of coronary artery disease and a prior carotid endarterectomy. This finding is consistent with the available evidence regarding the use of carotid stenting in clinical trials and registries to treat patients who are at similar or higher risk for carotid endarterectomy.33 After adjustment for patient characteristics, significant geographic variations persisted in carotid revascularization.

Finally, the 30-day mortality rate for carotid endarterectomy (1.2%) in 2005 was lower than the rates of 1.7% to 2.5% reported in a study from the mid-1990s31 but remains higher than the rates of 0.5% to 0.8% published in the studies32,33 that led to regulatory approval of the procedure. Likewise, the 30-day mortality rate for carotid stenting (2.3%) was higher than the rates reported in the initial randomized trial of carotid stenting with embolic protection devices (1.2%).34 Because this analysis was limited to elderly Medicare beneficiaries, the differences between the mortality rates we observed and those re-
ported in clinical trials are not unexpected. The differences likely reflect the differential selection of high-risk patients into the carotid stenting cohort, consistent with the CMS national coverage decision.

Our study has some limitations. First, Medicare claims data do not include information about symptom status, the presence of high surgical risk features such as contralateral carotid occlusion, the presence of significant coronary artery disease and heart failure, and patient preferences. These variables are unlikely to explain the substantial geographic variation we observed but may lessen some of the observed differences. Unmeasured clinical variables may also confound the relationship between observed covariates and the receipt of carotid revascularization in the multivariable model. Second, the absence of detailed clinical data prevented us from calculating risk-adjusted mortality rates. To adjust the comparisons on the basis of the available data—and therefore imply risk adjustment—would be misleading. Third, because we restricted the multivariable analyses to patients who underwent MRA or angiography (invasive or noninvasive), the results may not be generalizable to patients for whom revascularization was preceded by carotid ultrasonography only. Fourth, the analysis included only patients enrolled in fee-for-service Medicare, so the generalizability of the results to all Medicare beneficiaries is unclear. Finally, we observed patients from the time they became eligible for Medicare, so carotid revascularization in patients younger than 65 years is not reflected in the analysis.

Significant geographic variation was seen in the use of carotid endarterectomy and carotid stenting among Medicare beneficiaries and variation in the carotid imaging modalities used before revascularization. Moreover, men and patients with a prior diagnosis of peripheral vascular disease were more likely to undergo carotid revascularization, and patients with a prior diagnosis of coronary artery disease or a prior carotid endarterectomy were more likely to undergo carotid stenting. These findings suggest that the development of consensus regarding clinical criteria for carotid imaging, such as a national standard for appropriate use criteria, is required. Moreover, these data highlight important differences between patients who undergo carotid revascularization with carotid endarterectomy and those who undergo stenting with embolic protection. Ongoing clinical trials will provide critical guidance for the treatment of patients who are eligible for either method of revascularization.

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The Good, the Bad, and the About-to-Get Ugly

National Trends in Carotid Revascularization

The history of carotid endarterectomy (CEA) is a fascinating good news, bad news story. Wide geographic variations in the use of CEA have been noted for 3 decades, though its popularity has been cyclical. The use of CEA doubled in the early 1980s, but then dropped in half following reports of frequent complications and a national Medicare study reporting that one-third of CEA procedures were inappropriate. Subsequently, multinational randomized controlled trials (RCTs) found that, among carefully selected patients and surgeons, CEA reduced the risk of stroke and death compared with medical therapy. Symptomatic patients (with recent carotid stroke or transient ischemic attack), showed great benefit (absolute risk reduction in stroke of 8% per year) over 2 to 3 years. Asymptomatic patients had modest benefit (absolute risk reduction of 1% per year) over 5 years.

Good news followed these rare RCTs of surgery. Practice followed evidence and CEA use doubled. A population-based Medicare study also found dramatic declines in CEA for “inappropriate” and “uncertain” indications (32% to 9% and 32% to 4%, respectively), and non-RCT indications (70%-6%). The bad news was that despite the dramatic drop in overuse, nearly 1 in 11 CEA procedures were still deemed inappropriate, mostly in asymptomatic patients with high comorbidity. Paradoxically, there is also evidence that it is both underused and overused in minorities. There has also been “mission creep.” Carotid endarterectomy started out as revascularization for symptomatic patients, but now 70% to 80% of cases are for asymptomatic disease.

Carotid angioplasty and stenting (CAS), the less invasive but less well-proven endovascular alternative,