Regional Variation in Carotid Artery Stenting and Endarterectomy in the Medicare Population

Philip P. Goodney, MD, MS; Lori L. Travis, MS; David Malenka, MD, MS; Kristen K. Bronner, MS; F. Lee Lucas, PhD; Jack L. Cronenwett, MD; David C. Goodman, MD, MS; Elliott S. Fisher, MD, MPH

Background—To describe geographic variation in population-based rates of carotid artery stenting (CAS) and carotid endarterectomy (CEA) performed in Medicare beneficiaries.

Methods and Results—Medicare claims and enrollment data were used to calculate age, sex, and race-adjusted rates of CAS and CEA for Medicare beneficiaries in each of 306 hospital referral regions between 1998 and 2007. Procedures were identified using a combination of Current Procedural Terminology codes as well as diagnostic and procedural ICD-9 codes. Overall, the rate of carotid revascularization has fallen slightly over the last decade (3.8 procedures per 1000 in 1998, 3.1 procedures per 1000 in 2007; P<0.0001). Although the use of CEA decreased, from 3.6 to 2.5 procedures per 1000 beneficiaries in 2007 (P<0.0001), the use of CAS has increased >4-fold between 1998 and 2007, growing from 0.1 to 0.6 CAS procedures per 1000 beneficiaries (P<0.0001). Further, CAS rapidly disseminated across the country over the last decade. In 1998, 66% of hospital referral regions had a hospital that performed CAS; however, by 2007, nearly all (95%) hospital referral regions performed CAS (P<0.0001). Last, in regions with the highest utilization rates of CAS, it appeared that CAS was performed as a substitute for CEA. There was little evidence that CAS was being performed in addition to CEA, as no correlation existed between regional rates of CAS and CEA (r=0.06).

Conclusions—Even though CEA was used less frequently in 2007 than 1998, the use of CAS has grown significantly. Although regional variation in the use of CEA has remained fairly constant, regional variation has increased in the use of CAS. Given these changes in practice patterns, careful examination of the efficacy and cost-effectiveness of CAS is necessary. (Circ Cardiovasc Qual Outcomes. 2010;3:15-24.)

Key Words: revascularization ■ carotid endarterectomy carotid stenting regional variation

Carotid endarterectomy (CEA) has been well established for nearly 2 decades as the gold standard for stroke prevention from atherosclerosis of the carotid artery in both symptomatic and asymptomatic patients. Carotid artery stenting (CAS) has gained popularity in recent years, probably because of its perception as a less invasive procedure as well as the larger pool of potential providers (cardiologists, interventional radiologists, and surgeons) as compared with CEA (surgeons alone). In attempts to restrict the use of CAS to populations wherein its safety and efficacy has been demonstrated in randomized trials, the Center for Medicare and Medicaid Services (CMS) has restricted payment for CAS to only symptomatic patients deemed to be “high-risk” for CEA, either by anatomic or medical high-risk criteria.

As CAS has emerged into widespread clinical practice, it remains uncertain how rapidly this new technology has been implemented across the United States. Additionally, it remains uncertain how the growing use of CAS has affected the use of CEA. In carotid revascularization, debate as to how rapidly to adopt new procedures is not a novel concept. In the early 1990s, randomized trials demonstrated that CEA could provide effective stroke prophylaxis in both symptomatic and asymptomatic patients. With newfound enthusiasm for CEA came variation in utilization, and nearly 10-fold differences in procedural rates across regions were described. The implication of regional variation was not favorable; it was almost universally associated with poorer outcomes. For example, several investigators in the 1990s reported that within certain areas with high rates of CEA, greater than half of all CEs were performed with questionable indications, and 30-day stroke and death rates exceeding 5% were not uncommon. Studies such as these spurred efforts to decrease variation in the use of CEA through a variety of payer and physician led studies and initiatives.

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From the Section of Vascular Surgery (P.G., J.C.), Dartmouth-Hitchcock Medical Center, Lebanon, NH; the Department of Cardiology (D.M.), Dartmouth-Hitchcock Medical Center, The Dartmouth Institute for Health Policy and Clinical Practice (P.G., D.M., K.B., D.G., E.F.), Hanover, NH; and the Center for Outcomes Research and Evaluation (L.T., F.L.), Maine Medical Center, Portland, Me.


Correspondence to Philip P. Goodney, MD, Dartmouth-Hitchcock Medical Center, 1 Medical Center Dr, Lebanon, NH 03766.

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Given this history of regional variation and its effects on the use and effectiveness of CEA, we sought to investigate the possibility that CAS may also be subject to significant regional variation. Using CEA as a comparator, we used small area analysis to investigate the utilization of CAS in patients in the Medicare population in recent years.

WHAT IS KNOWN

- Carotid endarterectomy has been well established for nearly 2 decades as the gold standard for stroke prevention from atherosclerosis of the carotid bifurcation, in both symptomatic and asymptomatic patients.
- Carotid artery stenting has gained popularity in recent years, probably because of its perception as a less invasive procedure as well as the larger pool of potential providers (cardiologists, interventional radiologists, and surgeons) as compared with carotid endarterectomy (surgeons alone).

WHAT THE STUDY ADDS

- We found that whereas the use of carotid endarterectomy has declined significantly over the last decade, utilization of carotid artery stenting is increasing.
- Variation in the use of carotid artery stenting has also increased across regions, especially those regions of the United States where carotid artery stenting appears to be substituting for carotid endarterectomy.
- Our future work aims to understand the determinants of this variation as well as its effect on outcomes.

Methods

Databases
We used 20% national random samples from the CMS physician/supplier and denominator files for years 1998 to 2007 to identify all carotid revascularizations performed on Medicare-eligible beneficiaries during each of those years. The physician/supplier file contains all claims submitted by physicians for performance of procedures under the Medicare Part B program, including CPT codes, ICD-9 diagnosis codes, date of procedure, and the age, sex, and race of the beneficiary receiving the procedure. The denominator file contains information about eligibility by year for Part B and information about age, sex, and race of eligible beneficiaries. We excluded patients under age 65 or over age 99 and those with unknown race. We used t tests to compare rates between regions, and nonparametric tests of trend were used to test significance across years; probability values <0.05 were considered significant. All analysis was performed using SAS (SAS Institute, Cary, NC), and STATA 10 (College Station, Tex).

Procedure Selection
To examine each of the respective carotid revascularization procedures, we examined the incidence of their Current Procedural Terminology (CPT) codes over time. We used the CPT code 35301 to identify CEA during years 1998 to 2004. For CAS, explicit CPT codes (37215, 37216) were assigned in 2004 and did not appear in Medicare claims data until 2005. To establish an algorithm to identify CEA during years 1998 to 2004, we consulted with coding experts in vascular surgery as well as Medicare claims data until 2005. To establish an algorithm to effectively capture carotid stent procedures performed before 2005, we consulted with coding experts in vascular surgery as well as national experts on Medicare claims data. We developed a coding strategy designed to capture CAS procedures done specifically for carotid atherosclerotic disease. This strategy is outlined in Figure 1 and has been published previously. We selected all patients with a procedure code for peripheral stent insertion (37205 or 37206) and included only those who with a diagnosis code indicated that the procedure was performed for cerebrovascular disease. To avoid inclusion of patients undergoing peripheral stent placement in an artery other than the carotid artery, we eliminated any patient who had an ICD-9 diagnosis code for peripheral vascular disease (440.2 to 440.24, 443.8, 443.81, 443.9) as a diagnosis code in any position. For each procedure, we allowed 1 occurrence per person per day but otherwise allowed multiple events per person to reflect overall utilization.

Regional Variation in CEA and CAS
Regional variation in rates of overall carotid revascularization are shown in Figure 3A for the year 1998 and Figure 3B for the year 2007. The overall carotid revascularization rates largely reflect the regional rates of CEA, as CEA is performed much more commonly than CAS, even in the most recent years of our study. Areas of high utilization of carotid revascularization were found in the Southeast, the Midwest, and Northern Mid-Atlantic states. However, Rocky Mountain
Regional variation in CEA remained broad during our study period (Figure 4). Although many regions performed fewer than 2 CEAs per 1000 in 1998, many others regions performed more than 8 CEAs per 1000. The absolute range of regional variation extended from less than 1 CEA per 1000 to nearly 9 CEAs per 1000, whereas the interquartile range extended from 2.2 to 5.2 CEAs per 1000. For example, in Idaho Falls, Idaho, surgeons performed 0.3 CEAs per 1000, whereas surgeons in Munster, Indiana, performed 8.6 CEA per 1000. By 2007, the overall use of CEA had declined as described above, but the range of regional variation still remained broad, with an interquartile range extending from 1.2 to 3.7 CEAs per 1000. For example, in St Petersburgh, Florida, rates of utilization for CEA remained nearly twice the national average at both the beginning and end of our study period (7.2 per 1000 in 1998, 4.1 per 1000 in 2007).

Regional variation in CAS was initially quite small in 1998 (Figure 5). Many regions (32%) did not perform any CAS procedures in 1998. Even within the most aggressive regions, such as Elyria, Ohio, and Peoria, Illinois, utilization of CAS was low—this region performed fewer than 2 CAS procedures per 1000. However, by 2007, regional variation was much broader. Rates of CAS now ranged from 0 to >3 CAS procedures per 1000 (interquartile range, 0.1 to 1.1 CAS per 1000), with the highest rates being recorded in Davenport, Iowa, St Joseph, Michigan, Monroe, Louisiana, Rapid City, South Dakota, and Elyria, Ohio.

**National Dissemination of CAS**

In 1998, CAS procedures remained relatively uncommon in a significant number of regions across the United States because 98 (32%) of the 306 regions performed no CAS procedures in 1998. Although these locations were mainly located in the central and northwestern United States, regions in more densely settled areas such as Massachusetts (Worcester and Springfield), Florida (Gainesville, Bradenton, Lake-land, Ormond Beach, and St Petersburg), and California (Bakersfield, Palm Springs, San Luis Obispo, San Mateo, Santa Cruz, and Ventura) reported no CAS procedures in 1998. However, by 2007 CAS was performed in nearly every region in the nation. Only 16 (5%) of the 306 regions did not report a CAS procedure in Medicare patients, and these were typically in very rural areas in states such as Alaska, Colorado, Minnesota, and Idaho.

**Substitution or Addition?**

We next sought to determine whether these changes in CEA and CAS were a result of CAS being performed as a substitute for CEA or in addition to CEA. To investigate this, first we examined the possibility of substitution. To see the largest effect size, we studied those regions performing the most CAS procedures in 1998, as shown in Figure 6. (Data from HRRs with fewer than 11 events were suppressed to protect patient confidentiality.) In 1998, the 10 highest rate regions performed 0.1 to 0.6 CAS procedures per 1000, whereas 2 to 5 CEA procedures per 1000 were performed in...
those same regions. By 2007, several of these regions now performed more than 1 CAS procedure per 1000, whereas rates of CEA in these same regions declined to between 1 and 3 CEAs per 1000. These increases in CAS, matched by declines in CEA, suggest that substitution (rather than addition) underlies the increases in the rates of CAS in these regions.

Could these changes be a result of addition? If that were the case, regions with the highest CAS rates would also have the highest CEA rates. However, when we plotted regional rates of CEA in 2007 against regional rates of CAS in 2007, using the HRR as the unit of analysis, there was no such relationship (correlation coefficient, 0.06; Figure 7). Regions with high rates of CAS procedures were not necessarily the same as those regions with high rates of CEA. This finding makes it unlikely that addition explains the growth in CAS. It remains important to note, however, that these analyses are conducted at the HRR level, limiting interpretation of patient-level relationships between changes in the use of CEA and CAS.

Discussion

In our national analysis of carotid revascularization, we describe changes in the manner in which Medicare patients undergo treatment for cerebrovascular disease. First, as evidenced by our work as well as other published studies,21,23 CAS is now used more frequently. This increase has been mirrored by a slight decrease in the rate of CEA. Second, CAS has become widely disseminated, although there is still significant regional variation across the United States. Last, rather than being performed in addition to CEA, our study suggests that CAS is growing because it is substituting for CEA.

Why do the regional rates of surgical procedure vary, and why does it matter? This question has been asked before across several operations. In 1998, in a description of regional variation of several commonly performed surgical procedures, investigators demonstrated that most regional treatment variation occurred in clinical conditions in which the optimal treatment strategy was not clearly defined.7 For example, little regional variation exists in patients with hip fracture—the diagnosis is straightforward, and the well-agreed on treatment strategy is almost always surgery. Therefore, 10-fold variation across regions is seen in the use of surgical treatment of hip fractures. However, in procedures in which the indication for surgery is less easily established, or the treatment alternatives less well defined, more variation across regions was encountered. In this study, CEA rates varied nearly 10-fold and has been largely unchanged over time. In CAS, rates have developed over time to vary 6-fold.

Is regional variation always detrimental? Several investigators have investigated the effects of regional variation on the use and outcomes of CEA. In 1997, Wong et al13 studied 291 consecutive CEAs in Canada, across different regions with differing rates of utilization. Within high-utilization areas or surgeons, they found that nearly half of patients undergoing CEA had uncertain indications for surgery, and 1 in 5 patients underwent CEA inappropriately (such as for low-grade asymptomatic stenoses or for carotid occlusion). They concluded that the combination of questionable indications and high complication rates in their series (30-day stroke/death rate of 5.2%, cardiac complication rate of 8.9%).
possibly negated any overall surgical benefit, especially in asymptomatic patients.” In an older study, Winslow et al reviewed the indications for surgery in more than 1300 Medicare patients undergoing CEA in 1981. They found that more than one third underwent surgery inappropriately, and the stroke/death rate in the regions with high utilization approached 10%. Studies within the Veterans Administration population at that time echoed these findings. These studies, and others, raised concern about the use and appropriateness of CEA. Although the carefully constructed clinical trials that followed this unrest established clearer guidelines for the use of CEA, few would argue that significant regional variation in carotid revascularization is a good thing.

We believe that the lessons learned in the study of the effects of regional variation in CEA are applicable to CAS. Our study finds that in our current era, CAS rates now vary to an extent similar to CEA during its early evolution, despite payer-based attempts to limit its implementation to high-risk patients. Why does regional variation exist in the use of CAS? Some may argue that there are dramatic differences in patients across regions, with some regions having a higher proportion of patients with anatomic or medical high-risk criteria. Although it is difficult to refute this possibility on the basis of data presented in our report, this explanation seems unlikely. Several prior studies have shown that patient characteristics vary little across regions for CEA, and little evidence exists to suggest that CAS would be any different in this regard. Therefore, if this variation is not secondary to patient-level factors, its origin probably is secondary to physician- or hospital-level factors.

Variation in physician enthusiasm across specialties for the use of CAS probably explains the differences in utilization across regions. In prior work, several investigators have demonstrated that competing specialties may use invasive therapies differently. For example, a national study of the use of peripheral angioplasty found that regional rates of peripheral angioplasty procedures varied 14 fold across regions, and those regions where cardiologists provided the largest proportion of the procedures also had the highest utilization rates. Although different specialties may use new procedures differently, controversy may also surface in the way outcomes are measured after the new or evolving therapy. Our future work will aim to characterize the use and outcomes of CAS, by specialty, to understand more clearly the role that
the physician plays in determining regional variation in the use and outcomes of CAS.

Variation in hospital-level enthusiasm in developing programs for CAS may also play a role in the development of regional variation in CAS. Many believe that growth in health systems responds to the amount of care provided, described as “supply-sensitive care.”35,36 First studied at the University of California, Los Angeles, supply-sensitive care is a term used to describe the phenomenon that the capacity of a health care system is a major determinant of how much care is delivered to those who live in that particular region. Residents of a region with a high supply of hospital beds, specialists, and testing facilities tend to be admitted to the hospital more commonly, undergo more specialty consultations, and have more tests than those who live in a region with less capacity.37–39 For example, Nallomathu et al40 found that the opening of a specialty hospital focusing on percutaneous coronary intervention was associated with increasing population-based use of percutaneous coronary intervention within that region. Similarly, one might conclude that it is plausible that hospitals aggressive in establishing programs in CAS might also be most aggressive in using this technology. Our future work will aim to explore the ways in which CAS is used in different regions, both in areas of high utilization and low utilization.

What should be done, given our findings? First, we believe steps should be taken to ensure that regional variation in the use of CAS does not continue to expand. Future efforts by payers can guide patient selection to those groups demonstrated in trials to have the best results. For example, patients over age 80 have consistently shown poorer outcomes with CAS across several studies.41,42 Guidelines using evidence-based criteria such as age could decrease variation in the use of CAS. Second physicians could limit dissemination of research findings presented only in meeting abstracts or in press releases. For example, almost none of the early registry data in CAS was published in peer-reviewed journals. Instead, these findings were widely distributed by press releases and abstract presentation, without the opportunity for peer review.3 Several studies have demonstrated that information disseminated in this fashion often omits basic study facts and cautions, and the public may be misled about the validity and relevance of the science presented.43 Third, physicians could continue to educate patients about the risks involved in carotid revascularization. Currently, much of the information presented to patients about CAS comes from industry adver-
Several studies have shown that patients often misinterpret risks conveyed in the context of industry-sponsored advertisements. We believe the best materials to help inform patient decision-making will come from the physicians caring for patients with vascular disease, and educational efforts such as those by the American Heart Association and the Society for Vascular Surgery should continue.

Our analysis has several limitations. First, the CPT code specific for CAS, 37215/37216, was not routinely used by CMS during the time period contained in our analysis. Therefore, our analysis used a strategy of identifying patients...
undergoing CAS by both their diagnostic and procedural codes, indicating that a stent was placed for the indication of cerebrovascular disease in the absence of peripheral arterial disease. Even though this coding algorithm has been published previously by our group and others, some of these patients may have undergone vertebral artery stenting, or misclassification caused by coding error might have occurred. However, the proportion of vertebral stenting relative to CAS probably is quite small. Additionally, any misclassifications that may occur would not be systematically different from

year to year and are unlikely to represent unmeasured confounding within our findings. Our study shows differences in utilization of carotid revascularization, but whether or not this variation represents overutilization in higher use regions remains uncertain. To answer this question will require further study of the indications and outcomes of these procedures, especially across regions of differing intensity of care.

In conclusion, rates of overall carotid revascularization have fallen by more than 15% in Medicare patients over the last decade. Even though CEA was used 30% less often in 2007 than in 1998, the use of CAS has grown more than 4-fold. This growth has occurred largely because CAS has been used as a substitute for CEA. Although regional variation in the use of CEA has remained fairly constant, regional variation has increased in the use of CAS. Before this variation grows any further, careful examination of the efficacy and cost-effectiveness of CAS is necessary to ensure this new procedure measures up to its well-studied predecessor.

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Disclosures
None.

References


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