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Medicare's Policy on Carotid Stents Limited Use to Hospitals Meeting Quality Guidelines Yet Did Not Hurt Disadvantaged Groups

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Abstract

Medicare began covering carotid arterial stents in 2005 under an innovative policy that required hospitals to meet quality-of-care benchmarks prior to seeking reimbursement. By limiting hospital adoption, this policy may have inadvertently reduced availability of the stents among historically disadvantaged groups of Medicare beneficiaries. However, our analysis of hospitals that provided stents in 2005–2007 demonstrated that while 19–38 percent fewer hospitals offered them compared to similar technologies, availability of stents in localities with substantial poor, black, and/or rural populations was comparable to other areas. Medicare's coverage policy was followed by limited diffusion of new technology without adverse equity consequences.

Blockages (stenoses) in the carotid arteries, the primary arterial supply to the brain, are a major cause of stroke. Carotid arterial stents with cerebral protection are a potential alternative therapy to carotid endarterectomy for the treatment of carotid arterial stenoses. (1–5) First performed in 1954, endarterectomy is the standard surgical therapy, in which the blocked portion of the carotid artery is surgically excised. Delivered by catheters, carotid stents are wire-mesh tubes designed to maintain the patency of the carotid artery after a blockage has been treated by balloon angioplasty.

The U.S. Food and Drug Administration (FDA) approved the first carotid arterial stent in 2004,(6) and the Centers for Medicare and Medicaid Services (CMS) subsequently issued a national coverage decision that took effect in early 2005.(7) As part of its initiative to more assiduously apply clinical evidence and requirements for data collection to its coverage decisions,(8) Medicare designed its coverage in an unprecedented manner to restrict CMS reimbursement only to hospitals that had met a series of quality-of-care requirements.

Hospitals seeking to provide carotid stents to Medicare beneficiaries were required to apply for certification of significant prior experience with the devices, adequate facilities, comprehensive emergency management ability, practitioner certification, and participation in a carotid stent patient registry.(7)

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IMPORTANCE OF MEDICARE'S COVERAGE INITIATIVE FOR CAROTID STENTS

Medicare developed its 2005 coverage policy for carotid arterial stents in the context of increasing scrutiny of new technologies and their potential to deliver benefits to Medicare beneficiaries.(9) The Medicare program has historically been predisposed to cover new therapeutic technologies,(10) despite limited clinical evidence supporting their comparative effectiveness (11) and despite evidence from some clinical trials that included relatively few Medicare beneficiaries.(12, 13)

Also, Medicare has historically placed few restrictions on which hospitals could provide and seek reimbursement for new therapies, despite evidence that many hospitals often do not achieve clinical outcomes that would have been predicted by the results of clinical trials.(14, 15)

POTENTIAL ADVERSE CONSEQUENCES OF RESTRICTING TECHNOLOGY ADOPTION

This new coverage policy was intended to limit Medicare coverage for carotid arterial stents to institutions that were “competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes.”(7) To achieve this, CMS required hospitals to submit an affidavit asserting that a detailed list of facility standards specific to carotid stenting have been met, and to regularly submit registry data for all carotid stent recipients.

Hospitals are vital mediators of the therapeutic options available to patients in their vicinity, (16, 17) and health-care disparities can be explained in part by slow adoption of new technologies at hospitals situated in localities with large numbers of racial and ethnic minority patients.(18)

Furthermore, local provision of carotid stenting by hospitals is a very strong predictor of whether patients living in the locality are treated with carotid stents.(19, 20) While there are no Medicare coverage precedents that fully predict the policy consequences, a policy that restricted carotid stent provision to a smaller subset of U.S. hospitals than those typically adopting new cardiovascular technologies may have disproportionately reduced availability of this technology among minority, low-income, and rural patients. Such patients are often served by hospitals less able to meet increasingly stringent quality requirements.(21)

Disparate availability of new technology would limit the development of clinical evidence in these populations, which is a central aim of Medicare's Coverage with Evidence Development initiative.(11, 13) The goal of this research was to assess the effect of Medicare's innovative coverage policy on availability of this new therapy.

STUDY DATA AND METHODS

STUDY DATA

Our primary data were fee-for-service hospital claims from 2004–2007. Coding for high-cost procedures such as carotid stenting is typically the key element determining each claim's Medicare hospital payment amount, so it is highly probable that these data would accurately identify institutions that were providing carotid stents.

HOSPITAL SAMPLE SELECTION

We focused this analysis on the subset of U.S. acute-care hospitals that were potentially affected by Medicare's carotid stent coverage decision by including only those hospitals that had the technological capacity to perform invasive cardiovascular procedures in 2005–2007. These hospitals were empirically identified based on the following criteria: 1) continuous operation from 2004–2007, 2) performance of at least ten Medicare-reimbursed catheter-delivered stent procedures similar to carotid stenting (e.g., coronary, femoral, or renal stenting) during 2004, and 3) performance of at least thirty Medicare-reimbursed catheter-delivered stent procedures during 2005–2007. We excluded hospitals not located in the fifty states or the District of Columbia.

From this sample, we identified the hospitals that adopted carotid stenting after the March, 2005 CMS coverage decision; our source was Medicare's published online list of hospitals certified to receive Medicare reimbursement for carotid stenting.⁽²²⁾ We designated a hospital as a stent provider if it was both a member of this list as of December 31, 2007 and had submitted at least one Medicare stent reimbursement claim from March 17, 2005 to December 31, 2007.

COMPARISONS WITH OTHER TECHNOLOGIES

In order to compare utilization of carotid stents with utilization rates of endarterectomy, we examined International Classification of Diseases, 9th Revision procedure codes listed on Medicare institutional claims from March 17, 2005 to December 31, 2007 to identify carotid endarterectomy hospitals. For further comparison, we also identified hospitals that provided similar cardiovascular interventional technologies such as drug-eluting coronary stents (FDA-approved in 2003), implantable cardioverter-defibrillators (CMS expanded coverage in 2003 and 2005), and coronary artery bypass grafting (a well-established, fully defused technology). Hospitals that submitted at least five claims for a procedure between March 17, 2005 and December 31, 2007 were designated as a provider of that procedure.

ANALYTICAL APPROACH TO MEASURING TECHNOLOGY AVAILABILITY

We used the Dartmouth Atlas of Health Care's Hospital Referral Region, defined as a contiguous locality within which most inter-hospital cardiovascular referrals are contained, as the primary unit of analysis.⁽²³⁾ We determined that 85 percent of carotid stents or endarterectomies occur in the same referral region in which patients reside. It was not feasible to restrict the study only to patients with carotid disease, as there are no national data identifying patients who are appropriate candidates for carotid stents.

Without accurate "denominator" data, analyses of stent utilization at the patient level would be biased. Similarly, hospitals that specialize in the provision of procedures like carotid stenting would be likely to attract candidates for therapy from other hospitals. Thus, analyzing stenting rates using measures of race, income, or rural status aggregated at the hospital level would be confounded by patient "flow" between hospitals via referral pathways, self-selection, etc.

VARIABLES

We used Medicare enrollment information combined with U.S. Census data to designate hospital referral regions as high black population regions (n=61 of 306), low-income regions (n=76 of 306), and/or rural regions (n=202 of 306). We considered both region-level and hospital-level control variables in our analyses to account for other factors likely to influence a hospital's carotid stent adoption. These included region-level factors such as the burden of illness in the population, the degree of inter-hospital competition, and pre-existing

health care system capacity. They also included hospital-level factors such as volume, academic status, and hospital ownership (see Appendix for details).

MULTIVARIABLE STATISTICAL ANALYSES

We estimated multivariable logistic regression models predicting whether hospitals with the technological capacity to offer carotid stenting in 2005–2007 adopted it after the 2005 expansion of Medicare coverage. Three sets of predictor variables were used. The first set included only three hospital referral region-level predictors: high-black region, low-income region, and rural region.

The second set of predictor variables added other factors at the level of the region, including average risk severity of the patient population, the degree of inter-hospital competition, and health system capacity measures from the Dartmouth Atlas. The third full set of independent variables added hospital-level variables to the model, including each hospital's academic status, ownership classification, and hospital volume. Further regression details are described in the Appendix.

SENSITIVITY ANALYSES

We hypothesized that Medicare's coverage policy toward carotid stents was less likely to influence availability of treatment in localities where a substantial proportion of hospitals in the region already had provided carotid stenting prior to March, 2005 as part of clinical trials. Approximately 200 U.S. hospitals participated in these studies.^(5, 24, 25)

We therefore repeated our analyses after excluding regions ($n=71$) where more than 33 percent of cardiovascular procedure hospitals had been providing carotid stenting prior to 2005.

STUDY FINDINGS

HOSPITALS WITH TECHNOLOGICAL CAPACITY TO PERFORM CAROTID STENTING

We identified 1,479 U.S. hospitals with the technological capacity to perform carotid stenting based on their use of similar intravascular stenting procedures from 2004–2007 (Appendix). At least one such hospital was present in every hospital referral region, and high-black, low-income, and rural regions had slightly greater numbers of “cardiovascular” hospital beds per capita compared to predominantly white, higher income, and urban regions, respectively. Thus, there were no pre-existing deficiencies in availability of cardiovascular services in high-black, low-income, or rural regions.

By the end of 2007, 879 of these 1,479 hospitals (59 percent) had been certified by CMS to perform carotid stenting and had submitted at least one claim for the procedure (Exhibit 1). In early 2005, 235 out of the 306 hospital referral regions had less than 33 percent penetration of carotid stenting into their cardiovascular hospital markets, but only 42 regions continued to have less than 33 percent market penetration by late 2007 (Exhibit 2).

USE OF CAROTID STENTING COMPARED TO USE OF OTHER CARDIOVASCULAR PROCEDURES

We compared hospital utilization of carotid stents in 2005–2007 with concurrent use of four common interventional cardiovascular procedures at all 1,479 hospitals included in this study, as well as in the subgroup of 1,141 hospitals located in hospital referral regions without significant (i.e., less than 33 percent) early penetration (Exhibit 3). Overall, the hospital utilization rate of carotid stenting was 38 percent lower than that of carotid endarterectomy, 34 percent lower than use of drug-eluting coronary stents, 30 percent lower

than use of implantable cardioverter-defibrillators, and 21 percent lower than coronary artery bypass grafting at the same hospitals.

When we restricted analysis to those regions without substantial use of carotid stenting prior to CMS coverage, an even lower carotid stent hospital adoption rate (i.e., 52 percent of hospitals with technological capacity) was observed.

UNADJUSTED CAROTID STENT USE IN HIGH-BLACK, LOW INCOME, AND RURAL REGIONS

Among technologically-equipped hospitals located in high-black regions, 61 percent adopted carotid stenting versus 59 percent in predominantly white regions ($p=0.48$). Among hospitals located in regions in the lowest quartile of per capita income, 57 percent adopted stents versus 60 percent in higher income regions ($p=0.54$). Among hospitals in rural regions, 57 percent adopted the technology compared to 62 percent in urban regions ($p=0.08$).

ADJUSTED HOSPITAL USE OF CAROTID STENTING

In the first multivariable model predicting hospital utilization of carotid stents, hospitals in regions with large black populations, lower mean incomes, or rural areas did not have significantly different rates of stent use in 2005–2007 (Appendix). Adjustment for other region-level covariates indicated hospital use of the technology in areas with larger black populations was more common (odds ratio 1.51, $p=0.049$). However, addition of hospital-level covariates to the model caused the black population odds ratio to lose statistical significance (odds ratio 1.40, $p=0.17$). Thus, the full model confirmed no significantly different rates of carotid stent use among hospitals in high-black, low-income, or rural regions.

SENSITIVITY ANALYSIS EXCLUDING REGIONS WITH PRIOR CAROTID STENT USE

We then repeated our regression analyses on hospitals in the subset of hospital referral regions with low levels of carotid stent use prior to the 2005 coverage decision (in the other regions, all the hospitals that had provided carotid stenting prior to 2005 were certified and continued to provide stents after the national coverage decision). Among the 1,141 hospitals located in the 235 low-prior-use regions, there were again no statistically significant differences in the likelihood of adoption by hospitals in high-black, low-income, or rural regions compared to other hospitals.

DISCUSSION

Our results indicate that after Medicare's expansion of coverage for carotid stenting in March of 2005, carotid stents were adopted by a significantly smaller number of U.S. hospitals compared to the number of hospitals providing similar invasive cardiovascular procedures. However, the lower adoption rate did not result in inequitable availability of stents in areas with large black populations, lower average incomes, or in rural areas. Medicare's coverage policy was followed by a more limited number of hospitals delivering carotid stents to Medicare beneficiaries without unintended reductions in availability of this treatment to historically disadvantaged groups.

Medicare's carotid stent coverage policy was unique and innovative, in that no prior coverage decision had required hospitals to be certified for the provision of a particular technology in order to seek reimbursement for that technology. This policy was intended to enhance the quality of care received by Medicare beneficiaries undergoing carotid stenting

by requiring that hospitals wishing to perform the procedure meet a set of structural quality-of-care requirements.(7)

Prior evidence of suboptimal clinical outcomes among hospitals providing carotid endarterectomy to Medicare beneficiaries suggests that carotid revascularization (i.e., stenting or endarterectomy) outcomes may be particularly sensitive to hospital factors such as volume and adequate support services. Thus, policymakers may have viewed carotid revascularization as a particularly appropriate target for coverage policies that were institutionally focused.(15) While Medicare did not derive its list of carotid stenting quality-of-care requirements from outcomes data,(7) the certification requirements do represent a relatively uncontroversial list of factors likely to predict better clinical outcomes.

Medicare's coverage policy also recognized that carotid stenting was not a "proven" technology that is clearly superior to alternative treatments, thus providing ethical justification for limiting availability to a subset of Medicare beneficiaries nationwide.(26) Indeed, the absence of a nearby hospital offering stents in 2005–2007 was highly predictive of lower use among Medicare beneficiaries with carotid disease;(20) thus, availability of the technology in 2005–2007 was clearly not equal across the U.S. population of Medicare enrollees.

However, even in retrospect, the welfare effects of lowering the number of hospitals providing carotid stents are difficult to ascertain, as the carotid stent's effectiveness compared to alternative therapies such as carotid endarterectomy remains uncertain. While the Johnson & Johnson-supported Stenting with Angioplasty and Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) multi-center trial demonstrated therapeutic equivalence between carotid stenting and carotid endarterectomy for patients meeting the clinical characteristics that were incorporated in Medicare's coverage decision,(5) other studies have suggested that stenting outcomes may be inferior to endarterectomy.(2, 27)

Had Medicare enacted a less restrictive coverage decision with no requirement for hospital certification, this may have resulted in carotid stents being delivered to Medicare beneficiaries with lower quality of care and potentially worse outcomes at some centers. It is also possible, however, that Medicare's restrictive coverage policy resulted in worse outcomes by preventing patients who otherwise would have benefited from receiving stents. As the current study was not designed to examine how coverage policy affected clinical outcomes, this remains a critical area for future comparative effectiveness research.

Another important policy goal of Medicare's recent coverage decisions, including its Coverage with Evidence Development (CED) initiatives, was to collect "real world" patient data among Medicare beneficiaries to guide future expansion or modification of coverage (this was among the requirements imposed on hospitals for carotid stent coverage).(8, 11) A systematic bias in the availability of carotid stents among black, low-income, or rural patients under the limited coverage policy used for carotid stenting would have been antithetical to those goals, as data generated from these groups would have been sparse. The current study provides reassuring evidence that Medicare's coverage policy did not disproportionately reduce opportunities for receipt of carotid stents among historically disadvantaged groups, and thus the evidence developed from the coverage policy should not be biased by under-representation of these patients.

As technological innovation continues to drive the rising costs of health care,(28, 29) there is clearly a need for policies to move beyond blanket coverage of treatments by any willing provider toward more selective coverage requiring providers to demonstrate both their *a priori* ability to produce optimal treatment outcomes and their willingness to report data on patient outcomes.(8, 30) Our study provides important evidence consistent with the carotid

stent coverage policy's effectively limiting excess hospital adoption while simultaneously maintaining equitable technology availability.

It is possible that utilization rates of carotid stents in 2005–2007 among the hospitals included in our study would have been low even if Medicare's coverage policy had been less restrictive. Alternatively, if the hospital utilization rates of comparable cardiovascular technologies represent "full" adoption, the coverage policy for carotid stents may have reduced carotid stent adoption by between 200 and 550 U.S. hospitals (as illustrated in Exhibit 3)--a remarkable 19–38 percent reduction in the rate of hospital uptake.

It is noteworthy that use of carotid stenting in areas with larger black populations initially appeared higher than white areas, although addition of hospital academic status, ownership, and volume to the regression models appeared to explain this difference. A possible explanation is that restrictive coverage policies paradoxically favored availability of new treatments among patient groups that were more likely to receive care in high-volume and/or academic hospitals, which were the strongest predictors of carotid stent use.

LIMITATIONS

Our study was limited in its ability to adjust for concurrent policies and economic pressures that may have simultaneously influenced hospitals' decisions to adopt carotid stents. For example, until Oct 1, 2006 carotid stents were reimbursed under the same diagnosis-related group that covered carotid endarterectomy (i.e., 533–534). In 2006, CMS established a separate group for carotid stenting (577) in recognition of the unanticipated higher costs of that routinely exceeded the level of reimbursement for groups 533–534.(31)

It therefore is possible that hospitals not adopting carotid stenting were responding to the lower anticipated revenue from the procedure,(32) rather than to the CMS coverage policy. However, we did not observe a marked increase in carotid stent adoption rates in 2007, as would have been expected if reimbursement rates had been the operative factor in preventing hospital adoption in 2005–2006.

Another potential explanation of lower carotid stent adoption was the emergence of new clinical evidence during 2005–2007. Publication of the 2006 Endarterectomy Versus Angioplasty in Patients with Severe Symptomatic Carotid Stenosis (EVA-3S) trial(2) may have lowered enthusiasm for hospital adoption of carotid stenting, particularly in relation to more positive evidence emerging during the same time about the effectiveness of similar technologies (e.g. implantable defibrillators).(33)

It is possible that equal availability of new technologies at the level of the hospital referral region does not necessarily entail equal use of carotid stents among patients from different racial or socioeconomic backgrounds.(18, 34) However, it is also increasingly clear that some health care disparities are caused by the absence of availability in localities where historically disadvantaged groups are concentrated.(18, 35) Our findings encouragingly suggest that lack of local availability would not be a major contributor to any disparities in stent use.

Finally, our method of identifying hospitals with the technological capacity to adopt the procedure used arbitrary cutoffs for volume of use of related cardiovascular procedures. While prior use of comparable technologies has been shown to be highly predictive of a hospital's likelihood of adopting a new technology,(18, 36) it is possible that alternative methods of identifying hospitals as "technologically equipped" may have yielded different results. However, our main results were robust to variation in the threshold number of annual cardiovascular procedures used to define the study cohort.

GENERALIZABILITY

The carotid stent coverage policy and its aftermath provide a useful comparison to other Medicare technology coverage policies enacted at almost the same time. Limiting provision of advanced technological services to selected hospitals based on a technology-specific quality-of-care checklist appears to be a potentially more promising method of ensuring high-quality delivery of new technology than, for example, a device registry requirement alone.

The widespread adoption of implantable cardioverter-defibrillators was not significantly blunted by the registry requirement imposed by Medicare, although it is not clear if all hospitals providing defibrillator implantation would have been able to meet defibrillator-specific quality-of-care criteria had Medicare enacted defibrillator coverage in a manner similar to carotid stent coverage.

It is likely that similar CMS coverage policies would have different effects for different technologies. Hospital uptake of new technologies is influenced by published evidence on efficacy, peer-institution behavior, ease of implementation, the presence of clinical “champions,” manufacturer marketing, and the anticipated income stream.^(32, 37, 38) These factors vary substantially across new medical technologies, so it is uncertain that CMS coverage policies requiring hospital quality-of-care certification would inevitably produce similar hospital adoption patterns to that observed for carotid stents.

Nevertheless, the carotid stent policy experience presents a useful introduction to future possibilities of coverage combined with quality assurance.

SUMMARY

Following Medicare’s 2005 coverage policy for carotid stenting, substantially fewer hospitals adopted the technology during 2005–2007 than what would have been expected based on hospitals’ unrestricted utilization patterns of similar cardiovascular technologies. However, the lower rates of adoption did not result in reduced availability of the new treatment among historically disadvantaged groups of Medicare beneficiaries. The carotid stent coverage decision therefore may be a useful model for future CMS coverage decisions.

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Exhibit 1.**Carotid Stent Certified Hospitals: 2005–2007**

Source: Centers for Medicare and Medicaid Services' list of CAS-approved facilities. Notes: Rates of CMS certification of U.S. hospitals for the provision of carotid arterial stenting to Medicare beneficiaries. Dark red bars indicate U.S. hospitals newly certified during each calendar quarter. Lighter red bars indicate the cumulative number of U.S. hospitals certified prior to the calendar quarter.

Exhibits 2 and 3.**Hospital Referral Regions' Adoption of Carotid Stenting**

Sources: Medicare facility claims; Centers for Medicare and Medicaid Services' list of carotid-stent-certified facilities. Notes: Maps of U.S. Hospital Referral Regions indicating market penetration of carotid stenting in early 2005 (upper map) and late 2007 (lower map). Blue shading indicates regions with less than 33% market penetration.

Exhibit 4. Relative Use of Major Cardiovascular Technologies by U.S. Hospitals

Source: Medicare facility claims, October-December, 2007.

Notes: Utilization rates of carotid stents and comparable major cardiovascular technologies among the U.S. hospitals technologically equipped to provide interventional cardiovascular procedures. Blue bars indicate rates of use among all technologically equipped U.S. hospitals (n=1,449). Red bars indicate rates of use in the subset of U.S. hospitals (n=1,141) in hospital referral regions with low pre-2005 utilization of carotid stenting.