Multistate improvement in process and outcomes of carotid endarterectomy

Timothy F. Kresowik, MD,[a,b] Dale W. Bratzler, DO,[c] Rebecca A. Kresowik, BLS,[b] Marc E. Hendel, MS,[b] Sherry L. Grund, RN,[b] Kellie R. Brown, MD,[b,d] and **David S. Nilasena, MD,[e]** *Iowa City and West Des Moines, Iowa; Oklahoma City, Okla; Milwaukee, Wis; and Dallas, Tex*

Objectives: **The purpose of this study was to assess the effect of community-wide performance measurement and feedback on key processes and outcomes of carotid endarterectomy (CEA).**

Methods: **Complete medical record (hospital chart) review for indications, care processes, and outcomes was performed on a random sample of Medicare patients undergoing CEA in 10 states (Arkansas, Georgia, Illinois, Indiana, Iowa, Kentucky, Michigan, Nebraska, Ohio, Oklahoma) during baseline (Jun 1, 1995 to May 31, 1996) and remeasurement (Jun 1, 1998 to May 31, 1999) periods. In addition to review of the index hospital stay, hospital admissions within 30 days of the procedure were reviewed and the Medicare enrollment database queried to identify out-of-hospital deaths, to determine 30-day outcome results. The baseline data by state were provided to the Medicare Quality Improvement Organizations (QIOs) in the respective states, and quality improvement initiatives were encouraged.**

Results: **We reviewed 9945 primary CEA alone procedures, 236 CEA and coronary artery bypass grafting (CABG) procedures, and 380 repeat CEA operations during the baseline period (B), and 9745 primary CEA alone procedures, 233 CEA and CABG procedures, and 401 repeat CEA operations during the remeasurement period (R). There was a significant decrease in the combined event rate (30-day stroke or mortality) for CEA alone procedures between baseline and remeasurement (B, 5.6%; R, 5.0%). A decrease occurred in each of the indication strata; transient ischemic attack or stroke (B, 7.7%; R, 6.9%), nonspecific symptoms (B, 5.9%; R, 5.4%), and no symptoms (B, 4.1%; R, 3.8%). The combined event rate also decreased for CEA and CABG (B, 17.4%; R, 13.3%) and repeat CEA operations (B, 6.8%; R, 5.7%). The remeasurement period state-to-state variation in combined event rate for CEA alone ranged from 2.7% (Georgia) to 5.9% (Indiana) for all indications combined, from 4.4% (Georgia) to 10.9% (Michigan) in patients with recent transient ischemia or stroke, from 1.4% (Georgia) to 6.0% (Oklahoma) in patients with no symptoms, and from 3.7% (Georgia) to 7.9% (Indiana) in patients with nonspecific symptoms. There were significant increases in preoperative antiplatelet administration (62%-67%; $P < .0001$) and patching (29%-45%; $P = .05$) from baseline to remeasurement in the CEA alone subset. Preoperative antiplatelet administration and patching were associated with improved outcomes in the combined baseline and remeasurement data.**

Conclusions: **Community-wide quality improvement initiatives with performance measurement and confidential reporting of provider level data can lead to improvement in important care processes and outcomes. There is considerable variation between states in outcome and process, and thus continued room for improvement. Quality improvement projects that include standardized confidential outcome reporting should be encouraged. Preoperative antiplatelet therapy administration and patching rates should be considered as evidence-based performance measures. (J Vasc Surg 2004;39:372-80.)**

The efficacy of carotid endarterectomy (CEA) in stroke prevention for patients with symptomatic and asymptomatic carotid stenosis has been well-established in randomized trials.[1-5] Community-wide outcome surveys have often documented outcomes inferior to the results achieved in the randomized trials.[6-9] Some have advocated public reporting of outcomes as a necessary means of improving surgical outcomes in the community.[10] Others have used confidential feedback of hospital or physician level outcome data in multi-institutional quality improvement efforts.[11-13] An alternative or complementary performance measurement strategy to outcome reporting is the use of process measures. Process measures use care processes (eg, administration of preoperative antiplatelet agents before CEA) that have been linked to improved outcomes as indicators of quality. Process quality measures have the

From University of Iowa Carver College of Medicine,[a] Iowa City, Iowa Foundation for Medical Care,[b] West Des Moines, Oklahoma Foundation for Medical Quality,[c] Oklahoma City, Medical College of Wisconsin,[d] Milwaukee, and Centers for Medicare & Medicaid Services,[e] Dallas, Tex.

Competition of interest: The analyses on which this publication is based were performed under contracts, entitled "Utilization and Quality Control Peer Review Organization," sponsored by the Centers for Medicare & Medicaid Services, Department of Health and Human Services. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services; neither does mention of trade names, commercial products, or organizations imply endorsement by the US Government. The authors assume full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Centers for Medicare & Medicaid Services, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this Contractor. Ideas and contributions to the authors concerning experience in engaging with issues presented are welcome.

Presented at the Fifty-first Annual Meeting of the American Association for Vascular Surgery, Chicago, Ill, Jun 8-11, 2003.

Additional material for this article may be found online at www.mosby.com/jvs.

Reprint requests: Timothy F. Kresowik, MD, Department of Surgery, UIHC, 200 Hawkins Dr, Iowa City, IA 52242-1086 (e-mail: timothy-kresowik@uiowa.edu).

0741-5214/$30.00

doi:10.1016/j.jvs.2003.09.023

advantage of often requiring less risk adjustment than outcome measures, and are more readily actionable by health care professionals.

The Centers for Medicare & Medicaid Services (CMS) began the Health Care Quality Improvement Program (HCQIP) in 1992.[14] The HCQIP directed Medicare Quality Improvement Organizations (QIOs) to initiate quality improvement projects within their states. A number of these initiatives have been expanded to the national level.[15] A CEA pilot project was carried out as part of the HCQIP in 10 states. The baseline data from the 10-state CEA project has been reported.[9] The current report details the remeasurement data from this 10-state project after quality improvement activities were encouraged by the local QIOs.

METHODS

A complete medical record (hospital chart) review for indications, care processes, and outcomes was performed on a random sample of Medicare patients undergoing CEA (International Classification of Diseases, 9th revision, Clinical Modification [ICD-9-CM] procedure code 38.12, endarterectomy of vessels of head and neck) in 10 states (Arkansas, Georgia, Illinois, Indiana, Iowa, Kentucky, Michigan, Nebraska, Ohio, Oklahoma) during baseline and remeasurement 12-month periods separated by a 3-year interval. The sampling strategy was designed to obtain an adequate number of cases from each of the states, based on a power calculation using an estimated frequency of combined events (stroke or mortality) of 6% with a 95% confidence interval and SEM ± 1.5%. A 50% oversampling of the calculated individual state samples, except Iowa and Nebraska, which had 100% of cases selected because of ongoing CEA quality improvement projects, resulted in a sampling fraction that varied from 0.2 to 1.0.

In addition to review of the index hospital stay, hospital admissions within 30 days of the procedure were identified. The complete medical record from any of these hospital readmissions with an admitting or discharge diagnosis code suggesting a cerebrovascular accident (ICD-9 codes 430-438, cerebrovascular disease; 784.3, aphasia; 784.5, dysphasia; 342, hemiplegia; 344, paralysis) were reviewed. In addition to the review of hospital readmissions the Medicare enrollment database was queried to identify out-of-hospital deaths, to determine complete 30-day outcome results. The baseline sample (10,561 procedures) included discharges between Jun 1, 1995, and May 31, 1996. The remeasurement sample (10,379 procedures) included discharges between Jun 1, 1998 and May 31, 1999.

Requests for copies of the entire medical record for the primary admission and any readmissions were sent to the hospitals. Compliance with these requests is mandated by federal statute as part of participation in the Medicare program. The costs associated with copying and mailing medical records were reimbursed to the institution. A data collection tool was created for medical record abstraction by trained abstractors. Each medical record was comprehensively reviewed to determine patient demographic data, indication for the procedure, perioperative care processes, and postoperative outcomes. The records were reviewed by trained abstractors at a CMS Clinical Data Abstraction Center (DynKePRO, York, Pa). Data were abstracted from medical records directly into a computerized data entry system with an online edit check and data definitions to improve accuracy of data collection. Data definitions for procedure classification, procedural indication, and outcome have been described.[9]

For the original project and publication an extensive effort was made to validate the Clinical Data Abstraction Center abstraction process with respect to identification and classification (major vs minor stroke) of adverse outcomes. The medical records of all patients identified as having postoperative stroke after the initial chart abstraction were independently reviewed again by two clinicians with expertise in stroke. This process resulted in a slight decrease in the overall observed combined event rate, 5.6% unvalidated versus 5.2% after the independent clinician validation. The validation process was not performed for the remeasurement sample, and therefore for the purpose of this report the unvalidated data were used from the baseline sample to allow appropriate comparison with the remeasurement data.

The baseline data by state were provided to the Medicare QIOs in the respective states, and quality improvement initiatives were encouraged. The specific quality improvement efforts in the individual states were voluntary and not standardized. Four states (Georgia, Iowa, Ohio, Oklahoma) had projects focused on CEA outcomes that preceded the 10-state initiative.[6,13,16,17] These projects had all used review of hospital records of CEA admissions to determine outcome rates and provide institution level feedback. The Georgia, Iowa, and Ohio projects were statewide, while the Oklahoma project focused on eight hospitals. The Iowa project involved support of ongoing voluntary data collection and periodic feedback of process and outcome data. This approach was expanded to Illinois, Nebraska, and Oklahoma as part of the 10-state initiative. The QIOs in Indiana and Kentucky provided feedback of the data to institutions in their states and encouraged quality improvement efforts. No specific quality improvement projects were carried out in Arkansas or Michigan. All provider level (hospital or surgeon) data were confidential.

Data analysis. We examined simple descriptive statistics for the processes and outcomes of CEA care. We tested for the significance of the difference between the baseline and remeasurement samples with the Mantel-Haenszel χ^2 statistic as computed in Epi Info, version 6.

To examine the relative effect of different processes of care on CEA outcomes in the CEA alone subgroup, we first evaluated each process as an independent variable. To account for the effect of indication, each process was examined with a multivariate logistic regression model, with the combined event rate as the dependent variable. The independent variables in each model were dichotomous variables representing the process and each indication. PROC

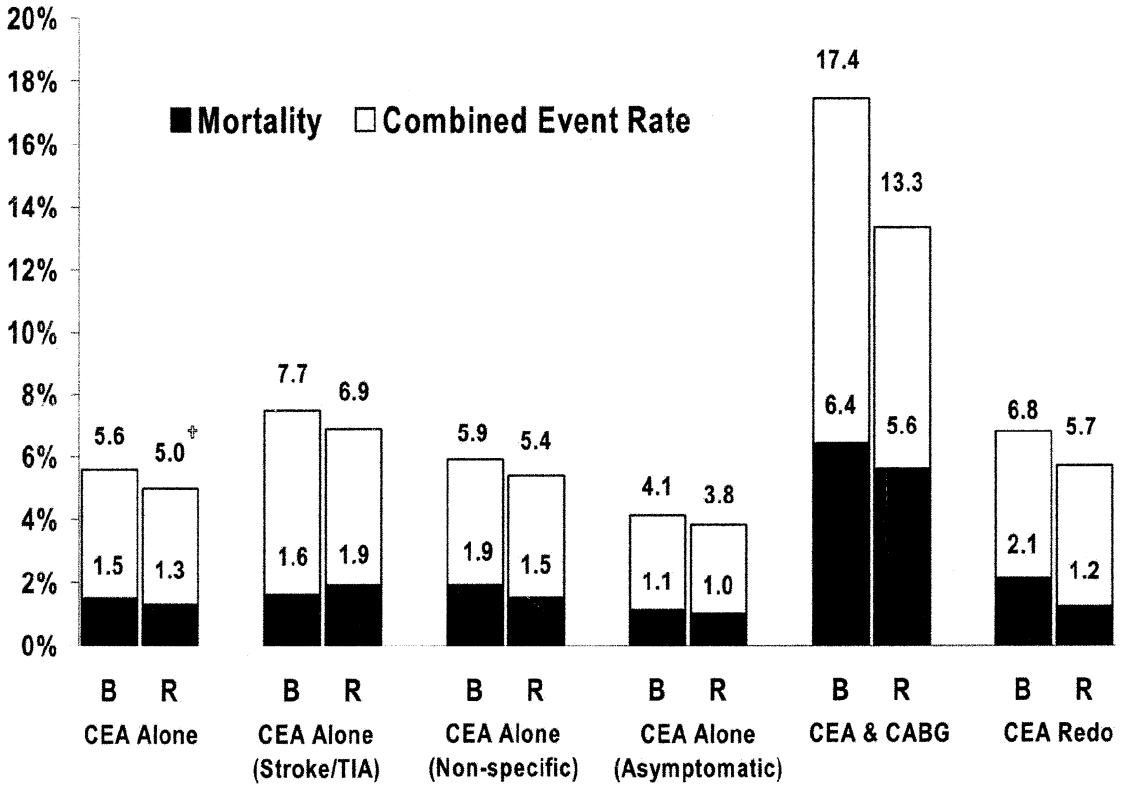

Fig 1. Combined event rate (30-day stroke or mortality) and mortality rate for 10-state aggregate for each procedure category: CEA alone, BN = 9945, RN = 9745; CEA and CABG, BN = 236, RN = 233; and CEA redo, BN = 380, RN = 401. CEA alone indication subsets: Stroke/TIA, BN = 2341, RN = 1852; nonspecific, BN = 3713, RN = 3800; and asymptomatic, BN = 3891, RN = 4093. *CEA,* Carotid endarterectomy; *TIA,* transient ischemic attack; *B,* baseline period, Jun 1, 1995, to May 31, 1996; *R,* remeasurement period, Jun 1, 1998, to May 31, 1999; *BN,* baseline number of procedures; *RN,* remeasurement number of procedures. †Significantly different from baseline to remeasurement, $P < .05$.

LOGISTIC (version 8.0; SAS Institute, Cary, NC) was used to compute the Wald χ^2 statistics.

RESULTS

The comparison between the baseline and remeasurement samples is displayed in Fig 1. A detailed comparison of the baseline and remeasurement samples including demographic data, processes, and outcomes is available in the Appendix (Tables I and II, online only). The combined event rate (30-day stroke or mortality) in the CEA alone subset decreased from 5.6% in the baseline period to 5.0% in the remeasurement sample ($P = .05$). In the baseline period 79% of strokes were ipsilateral to the CEA, and 60% occurred on the day of or the day after operation. In the remeasurement period the ipsilateral stroke rate was 76%, and 63% occurred by postoperative day 1. Although there were some changes in the indication distribution between baseline and remeasurement, the combined event rate decreased in each of the indication strata (transient ischemic attack or stroke, nonspecific symptoms, and no symptoms), indicating that the overall decrease in combined event rate was not a result of a change in indication distribution. The CEA and coronary artery bypass grafting combined event rate was 17.4% in the baseline sample and 13.3% in the remeasurement period. The repeat operation combined event rate was 6.8% in the baseline period and 5.7% in the remeasurement period.

The state-by-state comparison from baseline to remeasurement is displayed in Figs 2 and 3 and Table III. It can be seen that the state that was an outlier with respect to significantly higher combined event rates in the baseline CEA alone sample (Oklahoma) was no longer significantly different from the others in the remeasurement sample. The only state outlier for CEA alone (all indications combined) in the remeasurement sample was Georgia, which at 2.7% had a significantly lower combined event rate compared with the other states. Two states, Georgia and Oklahoma, showed a decrease in the combined event rate from baseline to remeasurement that was statistically significant ($P < .05$). Fig 3 shows that patching went up significantly in every state, but variation still exists.

The length of stay decreased from a median of 4.0 days in the baseline period to 3.0 days in the remeasurement period, although the postoperative median length of stay

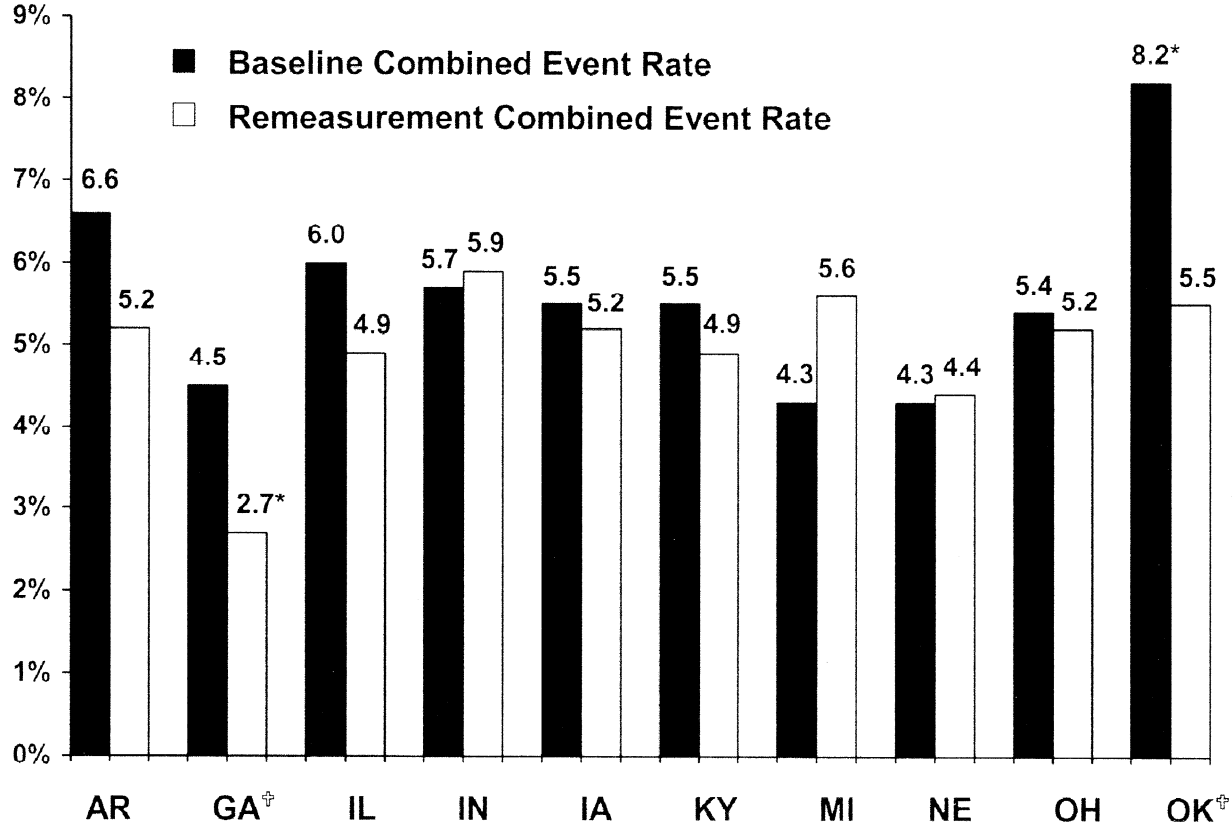

Fig 2. Combined event rate (30-day stroke or mortality) and mortality rate for CEA alone procedures (all indications) by state. Arkansas, BN = 770, RN = 828); Georgia, BN = 958, RN = 928); Illinois, BN = 1064, RN = 1035; Indiana, BN = 1026, RN = 1005; Iowa, BN = 1265, RN = 1260; Kentucky, BN = 892, RN = 846; Michigan, BN = 1141, RN = 1118; Nebraska, BN = 865, RN = 820; Ohio, BN = 1143, RN = 1125; Oklahoma, BN = 821, RN = 780. *CEA,* Carotid endarterectomy; *B,* baseline period, Jun 1, 1995, to May 31, 1996; *R,* remeasurement period, Jun 1, 1998, to May 31, 1999; *BN,* baseline number of procedures; *RN,* remeasurement number of procedures. *Significantly different from the mean, $P < .05$. †Significantly different from baseline to remeasurement, $P < .05$.

was unchanged, at 2.0 days. The proportion of patients with identified preoperative arteriograms was 71% at baseline and 64% at remeasurement. The rate of patching increased from 29% at baseline to 45% at remeasurement ($P = .05$), and preoperative antiplatelet therapy increased from 62% in the baseline period to 67% in the remeasurement period ($P < .0001$). With the combined CEA alone dataset (19,690 procedures from the baseline and remeasurement periods), preoperative antiplatelet therapy (odds ratio [OR} 0.73; $P < .0001$) and patching (OR, 0.88; $P = .05$) were associated with lower combined event rates in a model accounting for procedural indication (Table IV).

DISCUSSION

Quality of care and patient safety have been the focus of a great deal of interest in both the medical community and the public at large. The public interest has been sparked by media coverage of reports from the Institute of Medicine.[18,19] Various strategies have been proposed to stimulate quality improvement. One approach that is exemplified by the New York State Department of Health cardiac surgery project has been public reporting of outcome data.[10] The difficulty in collecting important clinical data, the lack of robust risk adjustment models, and the limited ability to properly define outcomes other than mortality have restricted the use of this approach for other surgical procedures. In addition, there is scant evidence that the public uses the information, and concerns have been raised about the potential adverse consequences of public reporting of surgeon-specific data, such as decreasing access to care for patients at high risk. For many procedures valid risk adjustment models are not available, and typical surgical volumes make statistically valid comparisons between surgeons or hospitals impossible.[20]

Because of the difficulties in standardized, risk-adjusted outcome reporting that can provide statistically valid surgeon or even hospital-level comparison for many surgical procedures, procedural volume has been proposed as an alternative "quality measure" for public reporting. This has been a major component of the Leapfrog initiative, which is

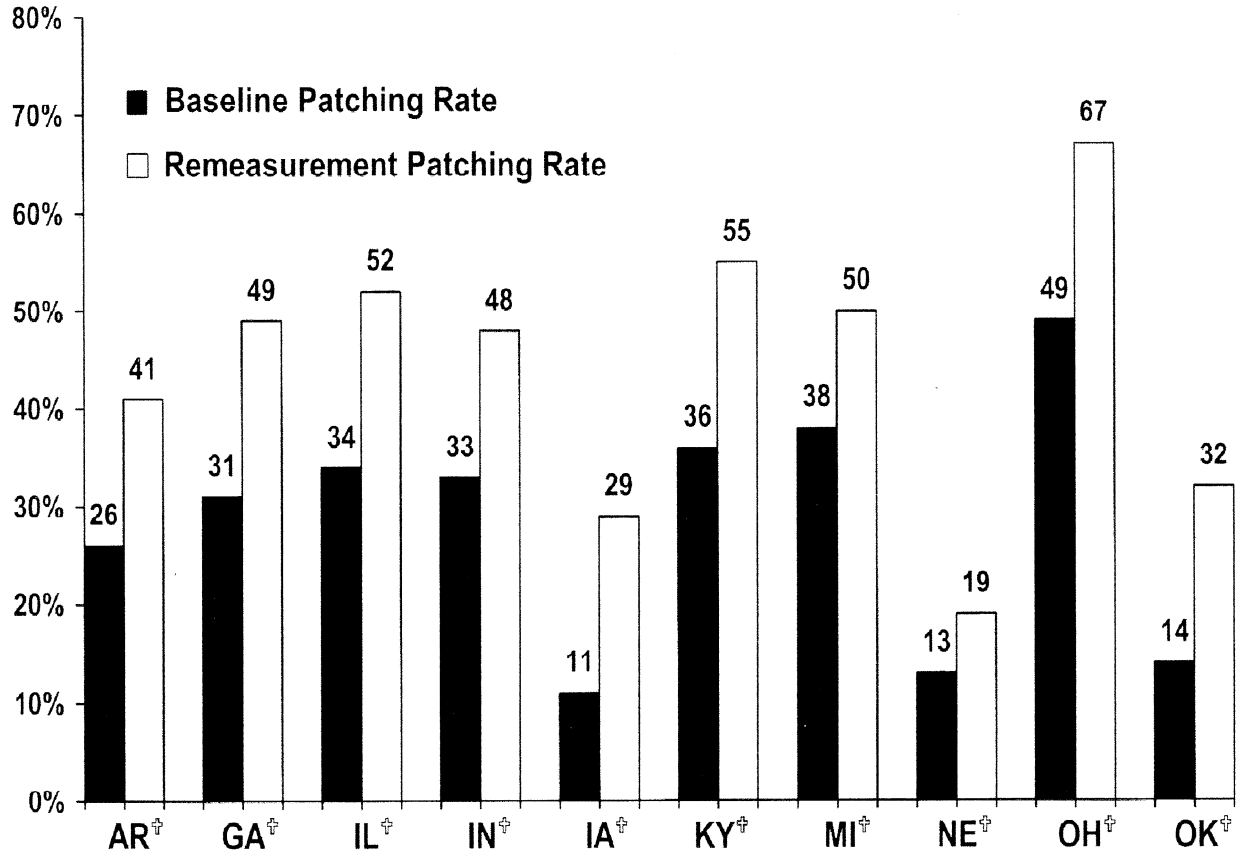

Fig 3. Use of patch angioplasty for CEA alone procedures (all indications) by state. CEA alone, BN = 9945, RN = 9745. *CEA,* Carotid endarterectomy; *B,* baseline period, Jun 1, 1995, to May 31, 1996; *R,* remeasurement period, Jun 1, 1998, to May 31, 1999; *BN,* baseline number of procedures; RN, remeasurement number of procedures. †Significantly different from baseline to remeasurement, $P < .05$.

an employer-funded effort to stimulate improved quality of care.[21] Reports on the relationship between volume and outcome for CEA show discrepant results.[22-27] Some high-volume surgeons have poor outcomes, and some low-volume surgeons have excellent outcomes. Even in the reports that have found a relationship between volume and outcome, the outcome differences have been small, and the thresholds for the volume effect at the hospital or physician level varied widely. Many of the reports suggesting a relationship between high volume and better outcomes have used administrative data that do not allow stratification by indications. The most important predictor of surgical outcome for CEA is the indication for the procedure. If indication is not taken into account, the volume-outcome relationship may be explained by the higher percentage of patients without symptoms operated on by high-volume surgeons.

An important concept in performance measurement is the unintended consequences or perverse incentives that some measures may create. Use of volume standards alone as a surrogate for true quality measurement may lead to inappropriate use. The variation in CEA use between states is substantial. We have demonstrated previously that the variation occurs in patients who do not have transient ischemia or stroke as the indication for the procedure (asymptomatic or nonspecific indications).[9] The benefit of CEA in patients without symptoms depends on very low procedural morbidity and mortality rates. If the message to surgeons is that quality is going to be measured by how many procedures are performed, it seems obvious how some will respond. If the use of volume standards alone for CEA leads to more procedures in patients without symptoms without monitoring of and improvement in adverse event rates, the overall result may be more adverse outcomes and cost to the system, rather than improvement in patient care.

An alternative approach to surgical quality improvement is the model used by the Northern New England Cardiovascular Disease Study Group (NNECDSG),[11] the Department of Veteran Affairs National Surgical Quality Improvement Project (DVANSQIP),[12] and this 10-state pilot project for CMS. These efforts used the confidential feedback of risk-adjusted outcomes to providers along with peer comparison. There are several advantages to confiden-

Table III. Outcomes (CEA alone): Remeasurement

	State										
	Ark	*Ga*	*Ill*	*Ind*	*Iowa*	*Ky*	*Mich*	*Neb*	*Ohio*	*Okla*	*All*
Stroke/mortality											
Stroke or mortality (%)	5.2	2.7	4.9	5.9	5.2	4.8	5.6	4.4	5.2	5.5	5.0
Mortality (%)	1.3	0.6	2.0	1.9	1.4	1.1	1.1	1.3	1.1	1.5	1.3
With major stroke	0.6	0.4	0.9	0.6	0.3	0.4	0.4	0.7	0.4	0.5	0.5
(No major stroke)	0.7	0.2	1.2	1.3	1.1	0.7	0.6	0.6	0.6	1.0	0.8
Nonfatal stroke (%)	3.9	2.0	2.9	4.0	3.8	3.8	4.6	3.0	4.2	4.0	3.6
Major stroke	2.3	1.4	1.8	2.1	1.6	2.1	2.7	1.6	2.1	2.6	2.0
Minor stroke	1.6	0.6	1.1	1.9	2.2	1.7	1.9	1.5	2.0	1.4	1.6
Stroke or mortality by indication (%)											
Ipsilateral stroke/TIA	5.3	4.4	7.9	6.3	7.1	4.8	10.9*	7.5	5.4	8.6	6.9
Nonspecific	5.8	3.7	5.2	7.9*	5.3	5.5	6.6	5.0	4.6	4.3	5.4
Asymptomatic	4.5	1.4*	3.2	3.9	4.3	4.3	2.5	2.3	5.8*	6.0*	3.8
Other outcomes											
Hemorrhage requiring return to OR	1.3	2.4	2.0	1.6	2.0	1.4	1.6	1.8	1.6	2.6	1.8
Cranial nerve injury	1.6	1.2	2.1	2.7†	2.2	1.2	2.1	1.5	2.4	1.2	1.9

TIA, Transient ischemic attack; *OR*, operating room.
*Indicates statistically significant difference from aggregate; $P < .05$, while controlling for indication.
†Indicates statistically significant difference from aggregate, $P < .05$.

Table IV. Process/outcome relationship (CEA alone, corrected for indication): Combined baseline and remeasurement datasets

Stroke or mortality as predicted by	P	*OR*	*95% CI*
Preoperative angiography	.62	1.04	0.90-1.19
Preoperative aspirin/ticlid*	<.0001	0.73	0.65-0.83
Local/regional anesthesia	.28	0.89	0.72-1.10
Use of heparin	.23	0.73	0.44-1.22
Reversal of heparin therapy	.74	0.98	0.86-1.11
Use of patch*	.05	0.88	0.77-1.00
Use of vein patch	.33	1.12	0.89-1.42
Use of prosthetic patch*	.01	0.83	0.72-0.96
Use of electroencephalagraphy	.56	1.05	0.89-1.24
Monitoring of backpressure	.37	0.88	0.67-1.16
Shunt, no monitoring	.58	0.97	0.85-1.09
No monitoring, no shunt	.29	1.09	0.93-1.27
Post-reconstruction assessment	.73	1.02	0.90-1.17

OR, Odds ratio; *CI*, confidence interval.
*Statistically significant predictor of stroke or mortality, $P < .05$, while controlling for indication.

tial feedback of outcome data. Since the specter of public disclosure is avoided, the likelihood of "gaming" the system by overestimating risk adjustment variables and avoidance of patients at high risk is decreased. The concern about statistical significance of individual comparisons is also lessened. By avoiding the public labeling of certain surgeons as "bad apples," a focus on quality improvement and moving the group toward the benchmark level is easier to achieve. There is no pressure to increase volume to meet some target level.

Another important component of this pilot project and the NNECDSG is the use of process measures, for example, preoperative administration of antiplatelet agents for CEA in this project. Process measures that are linked to better outcomes have advantages over outcome measures. Most process measures require less risk adjustment than outcome measures; thus statistically valid comparisons are more likely. Process measures are also more readily actionable by the physician; that is, they provide a specific means of quality improvement as opposed to outcome reporting alone. Most process measures are not susceptible to the unintended adverse consequences of outcome reporting and volume reporting discussed above. The major limitation of the use of process measures for surgical procedures is the limited number of processes with strong evidence links to better outcomes. Our data suggest that only preoperative administration of antiplatelet agents and patching are suitable process measures for CEA. Nonetheless, our data also suggest that there is room for improvement in both of these areas.

The overall improvement in combined event rate (death or any stroke) may seem modest (5.6%-5.0%). However, if one extrapolates from the approximately 92,000 CEA alone procedures performed in the Medicare popula-

tion nationally, this level of drop in adverse outcomes translates into more than 550 fewer deaths or strokes that year. If the national rate had been at the benchmark level achieved in the state of Georgia, more than 2100 additional strokes or deaths would have been prevented. The results in Georgia may be the most important outcome finding from this study. The overall 4.2% combined event rate and the 1.4% combined event rate in patients without symptoms demonstrates that benchmark outcomes can be achieved in the community setting across an entire state. The 1.4% event rate in patients without symptoms is remarkably similar to the 1.5% event rate that was observed by the surgeons in the Asymtomatic Carotid Atherosclerosis Study (ACAS), despite the fact that the rigid selection criteria for patients and surgeons in the trial were not applicable.[28]

The relatively high overall risk for death or stroke after CEA in asymptomatic patients (3.8%), observed even in the remeasurement period, is concerning. This level of adverse outcomes approaches the rate at which benefit is questionable. The ACAS trial results and the rate in Georgia demonstrate that a combined event rate of 1.5% is achievable in patients without symptoms. The observed postoperative combined event rate, however, should not be seen as a justification for alternative procedures to CEA. In the ACAS trial the stroke risk from angiography alone was similar to the surgical event rate. It is unlikely that adding angioplasty and stenting could be shown to have a lower event rate than the Georgia benchmark surgical results. It also seems likely that the increased rate of adverse events observed in this community-wide study, compared with research trials or selected institution results, is equally if not more likely to be seen for carotid angioplasty and stenting. The observations in this study should suggest the need for similar community outcome monitoring and reporting for carotid angioplasty and stenting, using the same indication and outcome definitions, rather than being a justification for the newer procedure.

Although we demonstrated significant improvement in combined event rate and key processes in the 10 states involved in this study, we cannot be sure that the improvement was a result of the efforts of the QIOs. Many other forces, including publications, may have influenced the outcomes and process rates in the 10 states. It should be emphasized that the quality improvement efforts by the individual QIOs were voluntary, as was the participation by individual providers within a state. The QIO in Georgia has had a statewide effort to improve CEA results that dates back 10 years, although we cannot be certain that the QIO effort alone led to the benchmark outcomes achieved.[16] The programs in the individual states were not standardized, and we cannot determine which interventions were associated with improvement. The size of the individual state samples did not provide adequate power to determine the relationship between intervention and improvement at a state level. We can say that the adverse outcome outliers improved in the remeasurement period.

We believe that quality improvement initiatives such as the NNECDSG, DVANSQIP, and this project should be encouraged in the future. Collecting relevant clinical data does pose a resource burden on the providers, and this must be recognized. It is important that standardized definitions of indications, risk adjustment variables, and outcomes be used for any comparisons. We suggest that the best quality indicator for public reporting for CEA is the participation in a standardized outcome reporting system that provides peer comparison and local peer review, rather than public reporting of the outcomes themselves. In addition, the CEA process measures of preoperative antiplatelet administration and patching might be appropriate measures for public reporting for any effort that has committed to public reporting of CEA data.

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Submitted Jun 6, 2003; accepted Sep 12, 2003.

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DISCUSSION

Dr A. R. Naylor (Leicester, England). This is an excellent paper. I listened to your original presentation in 2000, when you reported a 17% death/stroke rate after combined procedures. This, in fact, that was a catalyst for our group to do what now has become three very large systematic reviews on the natural history and results of staged and synchronous surgery.

You've reduced the risk to 13%. That's very commendable. But there is no evidence anywhere in the world literature that the risk for death and/or stroke with isolated CABG in patients with severe, asymptomatic carotid disease is anywhere remotely near that. Have you now stopped recommending combined procedures in these states now?

Dr Timothy F. Kresowik. I would urge you to look at Dr Kellie Brown's paper, which was presented last year at this meeting and published in the January 2003 issue of JVS.

One of the things we have to remember is that the combined carotid/CABG patients are a very high-risk group of patients. They're not just an average coronary bypass patient. So I think it would be unrealistic to compare them with typical coronary bypass patients.

What Dr. Brown found in that study was that most of the strokes have nothing to do with the ipsilateral carotid endarterectomy. I think the high complication rate reflects the severity of the disease of the patients. I would never say that the combined procedure should never be done, but I must say that we do it extremely rarely, and it would have to be for a symptomatic patient in both distributions.

Dr John J. Ricotta (Stony Brook, NY). Tim, I'd like to make a comment in reference to Dr Naylor's comment, and then I'd like to ask you a question.

Last month in *Stroke* we published a risk-adjusted analysis of combined carotid CABG, and found no statistically significant difference between what you would expect the stroke rate to be if you did the CABG alone and what you saw when you did the combined carotid CABG. I think this speaks to your point: that these patients are very different and that risk adjustment is extremely important.

You have done a nice job of demonstrating the so-called Hawthorne effect, that if you look at something you're going to improve the process. I wonder what you think we need to do to take the next step. You are still reporting very high rates. It seems to me that we've got to deal with the issues of accurate reporting rather than self-reporting, and we have to deal with the issues of risk adjustment. Whether a professional society like ours could play a role, whether this is something the federal government needs to do, or whether it's something that needs to be done regionally remains to be determined. However, I think if we're going to make more progress we have to move in that direction. I'd be interested in your thoughts on that.

Dr Kresowik. I think the key thing that I believe is that we need a standardized reporting mechanism, and it has to be very simple. Data collection should be based on using indication and outcome definitions that are standardized across the country. I also believe that the reporting mechanisms have to be local and confidential. I think it's been shown that the improvement that happened in New York associated with public reporting was due to the response of the surgeons and hospital staff, not to how the public chose their surgeon or hospital. I would like to see outcome reporting and quality improvement as a peer review process. I think the Society for Vascular Surgery should play a role in defining those indications strata and the outcome definitions.

Dr Peter K. Henke (Ann Arbor, Mich). Obviously, you're getting to the meat and potatoes that administrative database reviews can only touch on. And the reason is because you're able to review those patients' charts in depth. I wonder if you'd comment on how the new HIPAA regulations are going to affect the ability to do that. If you look at the majority of abstracts in this meeting, most are from retrospective reviews and from which we get very good knowledge. I think HIPAA is going to be a big detriment to research.

Dr Kresowik. I would agree. We've had the benefit as part of the quality improvement or peer review system that is clearly excluded from some HIPAA requirements in the regulations. There are certainly HIPAA issues that affect a lot of the other outcome and quality improvement research.

Dr James C. Stanley (Ann Arbor, Mich). This work raises questions regarding the data base from a random sampling of complete medical chart reviews versus that of an administrative discharge data base. A short while ago we published the outcomes of carotid endarterectomy reflected in an administrative database

(National Inpatient Sample) of more than 35,000 procedures performed over a 2-year period (J Am Coll Surg 2002;195:814-20). The most surprising outcome was that mortality and postoperative stroke rates after elective endarterectomy for high-volume surgeons (those performing more than 30 procedures a year) were 0.32% and 1.02%, respectively. Such outcomes were much lower than most benchmark data reported from statewide surveys such as presented today. Even among emergent endarterectomies being performed by low-volume surgeons (less than 10 procedures a year) mortality was only 1.68% and stroke rate was 2.50%. Perhaps more important were the differences in surgeon volume-related outcomes that were independent of hospital volume or specialty practice.

Although the information was confidential in your own database, was a surgeon-volume effect assessed? Our report was based on such large numbers that some of the vagaries of an administrative data base may have been cancelled out. In this day and age when initiatives like the Leapfrog project have placed such a great emphasis on hospital volume, it would seem important to segregate out such a simple factor as surgeon volume.

Dr Kresowik. It's a very important question, and a question I'd love to be able to answer. It's problematic for us in terms of individual surgeon identifiers in the hospital record. We have had problems with getting CMS to allow us to look at some of these questions, such as the importance of volume and/or specialty on outcomes.

An important issue is that most of the studies on the volume/outcome relationship for CEA using administrative data do not correct for indication for the procedure. Many high-volume centers and surgeons have a high volume of asymptomatic patients, who have a much lower risk for an adverse outcome.

The threshold for high volume changes from study to study. Many times in the published reports the effects of volume on outcome for CEA is quite weak. What I worry about is the perverse incentive associated with the message that high quality is always associated with the more you do. This message might create an incentive to operate on the wrong patients. The asymptomatic patient at high risk for complications because of medical comorbidities or with a low expected long-term survival should usually be treated non-operatively. I worry that the focus on volume alone will encourage surgeons to operate on more of these patients to increase volume. We have the ability with this data base, if we can get permission to do the linkages to the Part B claims system, to maybe address your question in a much more evidence-based manner.

Dr Richard P. Cambria (Boston, Mass). Quick question. You have a large data set. You mentioned the process of preoperative antiplatelet therapy. Have you looked at the data in terms of the effect of preoperative antiplatelet therapy?

Dr Kresowik. In terms of the risk reduction?

Dr Cambria. In terms of the morbidity of surgery.

Dr Kresowik. There was no association with return to the OR for bleeding with preoperative antiplatelet therapy, if that's the question.

Dr Cambria. The effect of preoperative antiplatelet therapy on complications, not bleeding complications, stroke, and death.

Dr Kresowik. There is a statistically significant risk reduction associated with preoperative antiplatelet therapy. The odds ratio was 0.73, and it's highly statistically significant.