Improving the outcomes of carotid endarterectomy: Results of a statewide quality improvement project

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Objective: The purpose of this study was to establish the statewide outcomes for carotid endarterectomy (CEA) and to facilitate improvement in outcomes through feedback, peer discussion, and ongoing process and outcome measurement.
Methods: The Medicare Part A claims files were used to identify all Medicare patients undergoing CEA in Iowa during two 12-month time periods (January 1994–December 1994 and June 1995–May 1996). Medical record abstraction was used to obtain surgical indications, perioperative care process, and outcome information. Confidential reports were provided to each hospital (N = 30) where the procedure was performed. Surgeons performing the procedure (N = 79) were invited to meetings to discuss care process variation and outcomes. Voluntary participation was solicited in a standardized program of ongoing hospital-based data collection of CEA process and outcome data.
Results: The statewide combined stroke or mortality rate decreased from 7.8% in 1994 to 4.0% in the 1995 to 1996 time period ($P < .001$). Fourteen hospitals, accounting for 74% of the statewide cases, participated in ongoing data collection. The combined stroke or mortality rate in these hospitals decreased significantly ($P < .05$) over time from 6.5% (1994) to 3.7% (1995-1996) to 1.8% (June 1997–May 1998). The use of intraoperative assessment of the operative site (20% in 1994, 46% in 1997-1998) and patch angioplasty (14% in 1994, 30% in 1997-1998) increased significantly during this time in the participating hospitals.
Conclusions: Confidential feedback of outcome and process data for CEA may lead to change in perioperative care processes and improved outcomes. Standardized community-based outcome analysis should become routine for CEA to ensure that optimum results are being achieved. (J Vasc Surg 2000;31:918-26.)

The value of carotid endarterectomy (CEA) in the treatment of both symptomatic and asymptomatic carotid occlusive disease has been demonstrated in randomized trials.[1-3] In these trials, researchers documented a statistically significant lower long-term stroke rate in the surgical groups versus patients receiving only medical therapy. Extrapolating the results from these trials to the general population of

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patients and surgeons requires some caution. The randomized trials excluded patients with comorbid conditions that would be associated with high surgical mortality and low long-term survival. Surgeons accepted for participation in the trials had to have documentation of patients with combined stroke or mortality rates that were deemed acceptable. Neither of these conditions are necessarily true for the entire population of patients undergoing CEA. Despite calls by vascular surgery leadership to focus on the results of procedures, many surgeons performing CEAs are unaware of their patients' stroke or mortality rates.[4-5] In some contemporary community-wide outcome studies, there have been reports of combined stroke or mortality rates similar to those achieved in the randomized trials, although many of these studies have been limited by relying on either administrative data or voluntary reporting.[6-15]

We developed a project to document the statewide outcomes of CEA and distribute confidential institution-specific outcome and care process reports to surgeons and hospital staff. Opportunities for discussion of outcome and process variation with surgeons from multiple institutions were provided. Institutions were recruited for a voluntary effort of ongoing data collection for CEA to facilitate continuous quality improvement. Outcome and process results over time, as well as comparison data, were provided to each of these participating institutions. This report details the results of the quality improvement effort.

METHODS

The Iowa Foundation for Medical Care (IFMC) is the Medicare peer review organization for Iowa. In 1992, the Health Care Financing Administration (HCFA) implemented the Health Care Quality Improvement Program.[16] This new initiative encouraged the use of quality improvement principles to improve health care for Medicare beneficiaries. As part of the health care quality improvement program, the IFMC has been performing statewide quality improvement activities for specific clinical topics affecting the Medicare population.

Data collection. In 1995 a project focusing on the outcomes of CEA was initiated. Iowa Medicare claims files were used to identify all CEA procedures performed on Medicare patients who were discharged between January 1, 1994, and December 31, 1994. All Medicare hospital claims (MEDPAR Part A) with a procedure code of 38.12 (endarterectomy of vessels of head and neck) from the International Classification of Diseases-ninth revision-Clinical Modification were selected. In addition, the Medicare Part B files (physician bills) were used to identify all Current Procedural Terminology (CPT) procedure codes of 35301. The Part A claims were also used to obtain all hospital readmissions within 30 days for the patients who were identified as having a CEA performed. The Medicare beneficiary data set was used to identify any deaths that occurred within 30 days of the procedure.

A data collection tool was created for medical record abstraction by trained abstractors. Information was obtained from each medical record regarding patient demographics, indication for the procedure, perioperative care processes, and postoperative outcomes. Chart review was carried out for both the index hospitalization and any readmissions within 30 days.

A second statewide data collection with centralized abstraction was carried out for all Medicare patients who underwent CEA in Iowa between June 1, 1995, and May 31, 1996, including hospital readmissions within 30 days and linkage with the Medicare beneficiary data set for postdischarge death. The third data collection period reported in this study was from hospitals that chose to participate in ongoing data collection using the *Project-in-a-Box* methodology described later. Although this data set includes all patients undergoing the procedure, only the Medicare subset is reported to allow comparison to the earlier time periods. The PIB data collection focused on the initial hospitalization, so only in-hospital complication rates are available. Further details on the second and third data collection periods, including processes to ensure reliability and validity, are provided in an appendix available on the web version of this manuscript.

Definitions. Indications for CEA were classified into four categories. Patients were considered to have *stroke* as the indication for the procedure only if they had documented ipsilateral hemispheric symptoms that persisted for more than 24 hours within 90 days before the procedure. Similarly, patients were considered to have *transient ischemic attack (TIA)* as the indication only if transient ipsilateral hemispheric symptoms occurred within 90 days before the procedure. Patients were considered to be *asymptomatic* only if there was no history at any time before the procedure of cerebrovascular symptoms or events in either the anterior or posterior circulations. All other patients (eg, those with remote symptoms, global or vertebrobasilar symptoms, contralateral hemispheric symptoms) were classified in a *nonspecific* category. These definitions

were used to create relatively clean indication groups of stroke, TIA, and asymptomatic with high reproducibility given the limitations of retrospective medical record review.

The CEA procedures were classified into three procedure groups. A *CEA with coronary artery bypass grafting (CABG)* included patients who had both CEA and CABG during the same operative episode. A *CEA reoperation* was used for patients who had a prior ipsilateral CEA. All other patients were included in a *CEA-alone* group. This report is confined to the CEA-alone subgroup.

For the purpose of outcome classification, *a postoperative stroke* was considered to have occurred if any new or worsening central nervous system deficit developed either during the hospitalization (in-hospital) or within 30 days after the procedure (30 day) and persisted for more than 24 hours. Postoperative strokes were classified as major or minor by looking at a point in time 5 days after the stroke, or on the day of hospital discharge, whichever occurred sooner. If patients had a new persistent deficit that resulted in a need for assistance with ambulation or eating or if patients had a new persistent aphasia, they were considered to have had a *major stroke*. Patients without disability were considered to have had a *minor stroke.* These relatively simple definitions allowed for reproducible classification by nurse abstractors using information typically available in the medical record. Deaths were considered *stroke related* if the death was associated with a major stroke. If there was no evidence of a major stroke associated with the death, the death was classified as *nonstroke* related.

Quality improvement interventions. The statewide outcomes of CEA (major strokes, minor strokes, other complications and deaths) in the state were stratified by the hospital. Hospital representatives were provided confidential reports on the outcomes and perioperative care processes for the procedure at their institution as well as statewide comparisons. Surgeons were invited to meetings to discuss the outcome data as well as perioperative care process variation. The actual medical records for patients classified as having postoperative strokes were available for confidential review by surgeons from the involved institutions.

Participation was solicited in a project of voluntary ongoing monitoring of care processes and outcomes using trained abstractors at each hospital. The PIB, a self-contained set of monitoring tools and intervention strategies, had been developed for several clinical conditions, including CEA, by the IFMC. The IFMC provides the data-collection tool, training of abstractors, data validation, and periodic feedback reports with institutional and statewide comparison data for each project. A total of 14 hospitals are participating in the CEA PIB ongoing data-collection process in Iowa. The significance of differences between time periods was evaluated using the Mantel-Haenzel χ^2 test with one degree of freedom (Centers for Disease Control and Prevention's Epi Info Version 6).

RESULTS

Table I displays the demographic and outcome data from the statewide data collection periods in 1994 and 1995 to 1996. In 1994 there were 798 CEA-alone procedures performed on Medicare patients in Iowa. These procedures were performed in 29 hospitals by 78 different surgeons. The combined stroke or mortality rate for these procedures was 7.8%. During this time period 20% of the procedures were performed on asymptomatic patients. During the 12-month period from 1995 to 1996, there were 1265 CEA-alone procedures performed on Medicare patients, an increase of 59%. During this time period, 79 different surgeons performed the procedure in 30 hospitals. The proportion of patients who were asymptomatic increased to 40%. The overall combined stroke or mortality rate was 4.0%. This drop (7.8% to 4.0%, $P < .001$) was only partially accounted for by the increased number of asymptomatic patients in the 1995 to 1996 period. The in-hospital combined stroke or mortality rate in patients with specific or nonspecific symptoms dropped from 9.1% to 4.6% ($P < .001$) between 1994 and 1995 to 1996. The overall mortality rate fell from 2.9% in 1994 to 1.1% ($P = .003$) during the time period of 1995 to 1996, and the nonfatal stroke rate decreased from 4.9% to 2.8% ($P = .05$). The median age of the patients (74 years) was unchanged in both 1994 and 1995 to 1996.

Table II provides a comparison of the in-hospital with 30-day morbidity / mortality results from the statewide 1994 and 1995 to 1996 data collection periods. The in-hospital combined stroke or mortality rate was 7.8% in 1994. Morbidity and mortality data obtained from the readmission record abstraction and HCFA beneficiary file for deaths indicated an 8.8% 30-day combined stroke or mortality rate for the same patient group. In the data period of 1995 to 1996, the in-hospital combined stroke or mortality rate was 4.0%, whereas the 30-day rate was 5.3%. During 1994 there was only one postdischarge death that occurred within the 30-day period. In 1995 to 1996, the postdischarge deaths

Table I. CEA (CEA alone) demographics and in-hospital outcomes—statewide

	Statewide (29 hospitals) *Jan 1994–Dec 1994*	*Statewide (30 hospitals)* *Jun 1995–May 1996*
Total no. of CEA-alone procedures	798	1265
Total no. of CEA-alone patients	726	1160
Median age (y)	74	74
Percent male	60%	59%
Percent asymptomatic	20%	40%
Combined stroke or mortality rate	7.8% (62 / 798)	4.0%* (50 / 1265)
By indication		
Ipsilateral stroke	6.3% (6 / 96)	7.0% (9 / 128)
Ipsilateral TIA	10.8% (21 / 194)	4.3%* (8 / 184)
Nonspecific	8.9% (31 / 349)	4.1%* (18 / 441)
Asymptomatic	2.5% (4 / 159)	2.9% (15 / 512)
Mortality rate	2.9% (23 / 798)	1.1%* (14 / 1265)
Stroke related	1.1% (9 / 798)	0.7% (9 / 1265)
Nonstroke related	1.8% (14 / 798)	0.4%* (5 / 1265)
Nonfatal stroke rate	4.9% (39 / 798)	2.8%* (36 / 1265)
Major	3.4% (27 / 798)	2.0%* (25 / 1265)
Minor	1.5% (12 / 798)	0.9% (11 / 1265)

*A statistically significant difference from 1994 ($P < .05$).

resulted in an increase in the mortality rate from 1.1% in-hospital to 1.7% at 30 days.

Table III displays the demographic and outcome data for Medicare patients from the 14 PIB hospitals during the three measurement periods. The 14 hospitals accounted for 550 (64%) of Iowa Medicare CEA procedures in 1994 and 938 (74%) of the Iowa cases during the 1995 to 1996 period. In the 12-month time period from June 1, 1997, to May 31, 1998, these hospitals reported 843 CEA-alone procedures. The median age of the patients in this time period was 74 years, and the proportion of patients who were asymptomatic was 46%. The combined in-hospital stroke or mortality rate dropped significantly in the 14 participating hospitals from 6.5% (1994) to 3.7% (1995-1996) to 1.8% (1997-1998) (1994 to 1995-1996, $P = .014$; 1995-1996 to 1997-1998, $P = .013$). The mortality rate decreased from 2.4% (1994) to 1.3% (1995-1996) to 0.6% (1997-1998) (1994 to 1997-1998, $P = .004$). The change in mortality from the 1995 to 1996 time period to the 1997 to 1998 time period was entirely due to the absence of stroke-related mortality in the latter time period. The stroke-related mortality was 0.7% in 1995 to 1996 and 0% in 1997 to 1998, whereas nonstroke mortality was 0.5% in 1995 to 1996 and 0.6% in 1997 to 1998. The major (disabling) stroke rate decreased from 3.1% (1994) to 1.7% (1995-1996) to 0.7% (1997-1998) (1994 to 1997–1998, $P < .001$). Although the percentage of patients who were asymptomatic increased dramatically between 1994 and 1995 to 1996 (22% and 40%), the trend leveled off, and the percentage of asymptomatic patients was 46% during the most recent time period.

Table IV provides the process data from the PIB hospitals during the three study time periods. There were significant care process changes occurring over the course of the study that may have influenced the improvement in outcomes from the baseline period. The proportion of patients receiving preoperative antiplatelet therapy with aspirin or ticlopidine increased from 66% in 1994 in the participating hospitals to 72% in 1997 to 1998 ($P = .02$). The percentage of procedures performed without cerebral monitoring or routine shunting decreased from 30% in 1994 to 24% in 1997-1998 ($P = .011$). In 1994, 14% of the patients received a patch closure. Patch angioplasty (both vein and prosthetic) use increased to 30% in 1997-1998 ($P < .001$). In 1994 only 20% of the patients had a documented intraoperative, postreconstruction evaluation of the operative site with angiography, B-mode ultrasound scanning, or Doppler scanning. These modalities were used in 46% of the patients in 1997-1998 ($P < .001$). Protamine reversal of heparin was used in 65% of cases in 1994 and 56% of cases in 1997-1998 ($P < .001$).

Table II. CEA outcomes—statewide (in-hospital vs 30-day)

	In-hospital	*30-day*
Iowa 1994 (n = 29)		
Combined stroke or mortality rate	7.8% (62/798)	8.8% (70/798)
Ipsilateral stroke	6.3% (6/96)	7.3% (7/96)
Ipsilateral TIA	10.8% (21/194)	11.3% (22/194)
Nonspecific	8.9% (31/349)	9.7% (34/349)
Asymptomatic	2.5% (4/159)	3.8% (6/159)
Mortality rate	2.9% (23/798)	3.0% (24/798)
Stroke related	1.1% (9/798)	1.3% (10/798)
Nonstroke related	1.8% (14/798)	1.8% (14/798)
Nonfatal stroke rate	4.9% (39/798)	5.8% (46/798)
Major	3.4% (27/798)	3.9% (31/798)
Minor	1.5% (12/798)	1.9% (15/798)
Iowa 1995-1996 (n = 30)		
Combined stroke or mortality rate	4.0% (50/1265)	5.3% (67/1265)
Ipsilateral stroke	7.0% (9/128)	10.9% (14/128)
Ipsilateral TIA	4.3% (8/184)	6.5% (12/184)
Nonspecific	4.1% (18/441)	5.4% (24/441)
Asymptomatic	2.9% (15/512)	3.3% (17/512)
Mortality rate	1.1% (14/1265)	1.7% (21/1265)
Stroke related	0.7% (9/1265)	0.9% (11/1265)
Nonstroke related	0.4% (5/1265)	0.8% (10/1265)
Nonfatal stroke rate	2.8% (36/1265)	3.6% (46/1265)
Major	2.0% (25/1265)	2.3% (29/1265)
Minor	0.9% (11/1265)	1.3% (17/1265)

DISCUSSION

The baseline data obtained in 1994 indicated that the morbidity and mortality for CEA in the Medicare population in Iowa was somewhat higher than was achieved in the randomized trials. The 30-day combined stroke or mortality rate in the 1994 symptomatic (stroke and TIA) patients was 10%, and in the asymptomatic patients it was 3.8%. The overall 30-day combined stroke or mortality rate in the North American Symptomatic Carotid Endarterectomy Trial (NASCET) (combined reports) was 6.5%.[1,2] The 30-day combined stroke or mortality rate in the Asymptomatic Carotid Atherosclerosis Study (ACAS) was 1.5% (excluding strokes reported for the intention of treating analysis that actually occurred preoperatively).[3] The overall CEA 30-day mortality rate for Medicare patients in Iowa in 1994 was 2.9%. The mortality rate in the NASCET was 1.0% and 0.1% in the ACAS.[1-3] Although the Medicare population is older and included patients with comorbid conditions that would have met exclusion criteria for entry in the randomized trials, the higher morbidity and mortality reduce the purported benefit of surgical therapy over medical therapy.

There were a number of other community-wide outcome studies focusing on CEA procedures performed since 1990. The studies vary in methodology, and comparisons are often difficult.[15] Researchers relying on administrative databases (claims or discharge data) are often unable to categorize patients by indication, and reporting of complications may be incomplete.[6-8] Voluntary registries can be limited only because of the inclusion of data from select surgeons (eg, vascular society registries) or because of reporting bias.[12-14] In recent studies where chart review was used, researchers have generally reported overall combined stroke or mortality rates in the 5% to 6% range.[9-11]

The major goal of our project was to see if a statewide quality improvement effort could result in a reduction in the surgical morbidity and mortality. A cornerstone of quality improvement is measurement. An initial step was the development of the tools that would allow measurement at the individual provider level to track progress over time and allow peer com-

Table III. CEA demographics and in-hospital outcomes: participating hospitals (n = 14)

	Jan 1994–Dec 1994	*Jun 1995–May 1996*	*Jun 1997–May 1998*
Total no. of CEA-alone procedures	550	938	843
Total no. of CEA-alone patients	504	869	787
Median age (y)	73	74	74
Percent male	61%	59%	62%
Percent asymptomatic	22%	40%	46%
Combined stroke or mortality rate	6.5% (36/550)	3.7%* (35/938)	1.8%*† (15/843)
By indication			
Ipsilateral stroke	7.1% (5/70)	6.4% (6/94)	4.2% (3/72)
Ipsilateral TIA	8.5% (11/130)	4.5% (6/133)	3.9% (5/128)
Nonspecific	8.2% (19/231)	2.7%* (9/332)	1.6%* (4/253)
Asymptomatic	0.8% (1/119)	3.7% (14/379)	0.8%† (3/390)
Mortality rate	2.4% (13/550)	1.3% (12/938)	0.6%* (5/843)
Stroke related	1.1% (6/550)	0.7% (7/938)	0.0%* (0/843)
Nonstroke related	1.3% (7/550)	0.5% (5/938)	0.6% (5/843)
Nonfatal stroke rate	4.2% (23/550)	2.5% (23/938)	1.2%*†(10/843)
Major	3.1% (17/550)	1.7% (16/938)	0.7%*(6/843)
Minor	1.1% (6/550)	0.7% (7/938)	0.5% (4/843)

*A statistically significant difference from 1994 ($P < .05$).
†A statistically significant difference from 1995-1996 ($P < .05$).

parison. Although there is a strong evidence base (the randomized controlled trials) for the expected outcome measures, the evidence base for many of the CEA process measures, with the possible exception of antiplatelet therapy, is lacking.[17] Our approach was to report the process measures that may result in better outcomes (eg, intraoperative monitoring of cerebral perfusion to determine the need for shunting; intraoperative, postreconstruction assessment of the operative site; use of patch angioplasty) without using these measures as quality indicators per se.

The key risk adjustment variable for comparison of CEA outcomes is the symptom status of the patient. Any retrospective, medical record abstraction-based project has limitations with respect to categorization of patients. In addition to the scarce documentation found in some medical records, terms such as *transient ischemic attack* or *stroke* are often used in a nonspecific manner. We chose to define strict categories of stroke, TIA, and asymptomatic with classification of all other patients in a nonspecific category. This allowed comparison to the benchmarks achieved in the randomized trials for the symptomatic and asymptomatic patients. Patients were categorized as having TIA or stroke as an indication for the procedure only if they had recent (< 90 days) ipsilateral, hemispheric symptoms or imaging evidence, in the case of stroke. Patients with remote, contralateral, or posterior circulation symptoms were included in the nonspecific category. For example, patients with contralateral or posterior circulation symptoms and an occluded contralateral carotid are likely to have a higher surgical risk than completely asymptomatic patients, although strictly speaking, the ipsilateral carotid territory is asymptomatic. In our data set this type of patient was included in the nonspecific category. Despite our strict definition of asymptomatic, the asymptomatic group accounted for almost half of the patients undergoing CEA in the most recent time period. Our asymptomatic group should have had a stroke risk at least the same as, if not lower than, a group of patients with the asymptomatic hemisphere definition.

The importance of risk adjustment of the combined stroke or mortality rate based on indication is illustrated in comparing the statewide results in the 1994 and 1995 to 1996 time periods. The number of cases markedly increased by 59% between these two periods. Only 5% of this increase was in patients with TIA or stroke as the indication for the procedure. The increase was almost certainly related to the publication of the results of the ACAS, and 75% of the increase was in patients in the asymptomatic category. As expected, the combined stroke or mortality rate in the asymptomatic patients was lower than in those with specific or

Table IV. CEA processes: participating hospitals (n = 14)

	Jan 1994-Dec 1994	*Jun 1995-May 1996*	*Jun 1997-May 1998*
Antithrombotic therapy			
Preoperative aspirin or ticlopidine	65.8% (362/550)	69.5% (652/938)	71.9%* (606/843)
Intraoperative heparin	99.5% (547/550)	98.5% (924/938)	98.7% (832/843)
Heparin with protamine	65.4% (358/547)	52.2%* (482/924)	56.4%* (469/832)
Monitoring of cerebral perfusion			
Local/regional anesthesia	21.3% (117/550)	24.4% (229/938)	18.7%† (158/843)
EEG	30.7% (169/550)	32.7% (307/938)	25.4%*† (214/843)
Back pressure	8.0% (44/550)	9.1% (85/938)	14.1%*† (119/843)
Transcranial Doppler scan	0.0% (0/550)	0.1% (1/938)	6.5%*† (55/843)
Shunt, no monitoring	20.2% (111/550)	18.1% (170/938)	20.9% (176/843)
No shunt, no monitoring	29.8% (164/550)	27.3% (256/938)	23.7%* (200/843)
Patch grafting			
Vein	10.7% (59/550)	1.4%* (13/938)	1.8%* (15/843)
Prosthetic	3.5% (19/550)	12.0%*(113/938)	28.4%*† (239/843)
Postreconstruction assessment			
Angiogram	0.5% (3/550)	0.7% (7/938)	0.0%*† (0/843)
Ultrasound image/duplex scan	4.2% (23/550)	4.6% (43/938)	6.0% (51/843)
Doppler scan	14.9% (82/550)	23.5% (220/938)	39.6%*† (334/843)

*A statistically significant difference from 1994 ($P < .05$).
†A statistically significant difference from 1995-1996 ($P < .05$).
EEG, Electroencephalogram.

nonspecific symptoms, and the changes in indication distribution alone would be expected to result in an overall decreased morbidity/mortality. Because the outcomes could be stratified by indication, it was noted that the marked decrease in combined stroke or mortality rate between 1994 and 1995 to 1996 was not solely due to a rise in the proportion of asymptomatic patients (Tables I and III). This is illustrated by the decrease in the combined stroke or mortality rate from 9.1% to 4.6% in the patients with specific and nonspecific symptoms.

Record review was necessary for accurate determination of the complications, in addition to providing the necessary data for risk adjustment. Although the HCFA beneficiary file is an accurate source of information about mortality and is useful in tracking postdischarge mortality, administrative claims data are not accurate regarding the documentation of the occurrence of postoperative strokes. The stroke codes are sometimes used for both preoperative and postoperative events, and many postoperative strokes are not reflected in claims data. Our medical record review also allowed some measure of the severity of the postoperative stroke. The simple definition of major stroke (new or worsening difficulty with walking or eating, which results in the need for assistance, or difficulty communicating, at 5 days after the event) allowed reproducible categorization from information available in most medical records. More complex stroke scales would only be useful in prospective data collection. The use of chart abstraction also allowed us to collect care process information (use of antiplatelet agents, intraoperative monitoring of cerebral perfusion, patching, reversal of heparin, postreconstruction assessment) that would not be available from administrative data.

The ongoing hospital-based PIB data collection effort focused on in-hospital outcomes. Obtaining 30-day outcomes is difficult using hospital-based abstraction because patients with complications may not always return to the same institution. Obviously, in-hospital and 30-day outcomes should not be compared, but it is our opinion that in-hospital outcomes are useful for peer and longitudinal comparison. Most adverse outcomes occur before hospital discharge, as was demonstrated in our statewide data collection periods (Table II).

A criticism of the onsite data collection methodology used for PIB is the theoretical possibility of selective or altered reporting by providers. We believe this possibility has been minimized first and foremost by the confidential, quality improvement focus of this effort as opposed to efforts involving public disclosure and accountability. The New York Coronary Artery Bypass Study is an example of an accountability effort that may have contributed to an overall decline in CABG procedural morbidity and mortality in that state.[18] This public disclosure approach also created a strong incentive for

providers to avoid high-risk patients and possibly "game the system" by overestimating risk variables. Our approach to improving outcomes was more in line with the model of the Northern New England Cardiovascular Diseases Study Group.[19] Because the focus in our study was on quality improvement with discussion of process differences by surgeons, but confidential outcomes data release, the incentive for selective or altered reporting is reduced. Another advantage of a quality improvement versus an accountability approach to outcomes analysis is the ability to provide useful information with smaller denominators. If this project were designed for accountability or public disclosure, the large numbers required to have statistical assurance that individual reported rates are valid estimates of the true complication rates would not have been achieved for many surgeons and hospitals in this project.

There were significant improvements in outcomes seen during the course of our study, which were documented in both the overall statewide sample and the hospitals participating in the PIB. The outcome improvements were seen in all indication categories. We believe that the improvements were related to the feedback of the data, in addition to peer discussion of the process and outcome results. Local feedback of data in this fashion has been shown to alter physician behavior even when corrected for national trends.[20] We also identified significant changes in many of the process measures over the course of the study, with the increases in patching and intraoperative assessment of the operative site being the most dramatic. Obviously, this type of retrospective study cannot determine the relationship between those process measures and the improved outcomes. It is possible that other factors may explain some of the improvement that occurred. Patient selection and / or changing referral or practice patterns likely also play a role.

CONCLUSIONS

The results reported in this study suggest that confidential feedback of outcome and process data for CEA may lead to changes in process and improved outcomes. It is our opinion that outcome measurement is best accomplished with a quality improvement approach rather than with an accountability / public disclosure effort. We believe that it is incumbent on every surgeon performing CEA to participate in some form of standardized outcome assessment. Surgeon and hospital level outcome analysis is necessary to ensure that optimum results are being achieved.

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APPENDIX

The second data collection period in Iowa (June 1995-May 1996) was part of a HCFA-sponsored 10-state CEA quality improvement effort led by the IFMC. A data collection tool was developed by the IFMC using the definitions from the original project. Medicare Part A claims files were used to identify patients with a procedure code of 38.12 from the International Classification of Diseases-ninth revision-Clinical Modification discharged between June 1, 1995, and May 31, 1996. In Iowa, all Medicare patients meeting these criteria during that 12-month time period were selected for analysis. The records were reviewed initially by trained abstractors at a HCFA Clinical Data Abstraction Center (DynKePRO, York, Penn). All Iowa patients designated as having strokes were reviewed by two nurse reviewers (SLG, MAB), who led the data collection tool development and abstractor training efforts throughout the project. The strokes were also validated by two physician reviewers. Disagreements were arbitrated by the lead author (TFK). In addition to the patients identified as having postoperative strokes, a subset of patients classified as having no postoperative stroke was subject to the same validation process. The subset chosen was based on administrative characteristics (hospital length of stay > 5 days, discharge codes suggesting postoperative neurologic complications, and discharge other than to home) that had been shown to be associated with postoperative strokes. The PIB data used included all CEA patient discharges from the 14 participating hospitals in the 12 months between June 1, 1997, and May 31, 1998. The first 15 records submitted from each institution were reabstracted by IFMC nurse abstractors to validate the on-site abstraction and to facilitate training of the hospital-based abstractors. All strokes identified during this time period were validated by SLG, MAB, and TFK.