Surgical outcomes research

Five-step protocol for carotid endarterectomy in the managed health care era

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Background. *We developed a protocol combining 5 cost-effective strategies to determine whether elective carotid endarterectomy (CEA) could be performed safely without adversely affecting well-established low morbidity and mortality rates and with significant hospital cost savings.*
Methods. *Between April 1, 1995, and December 31, 1996, 109 of 141 patients were prospectively enrolled as candidates into a 5-step CEA protocol: (1) duplex ultrasonography (DU) performed at an accredited vascular laboratory as the sole diagnostic carotid preoperative study, (2) admission the day of operation, (3) cervical block anesthesia to eliminate intraoperative electroencephalogram monitoring, (4) transfer from the recovery room after a 4-hour observation period to the vascular ward, and (5) discharge the first postoperative morning. The other 32 patients were excluded from analysis; 16 patients were treated by vascular surgeons not participating in the protocol, 9 were treated concomitantly for other medical problems, and 7 were admitted emergently.*
Results. *One patient died of carotid hemorrhage the first postoperative morning, and one had an intraoperative embolic stroke for a combined mortality-stroke rate of 1.8% (2 of 109). Of the 109 patients, 70% (76) underwent operation using DU as the sole diagnostic study, 95% (104) were admitted the day of operation, 76% (83) had cervical block anesthesia, 59% (64) were transferred to the floor the day of operation, and 83% (90) were discharged the morning after operation. None of the 109 patients were adversely affected by these 5 cost-saving strategies except potentially the patient who bled the first postoperative morning. The predicted charges of a patient treated with a perioperative protocol that many vascular surgeons currently use (preoperative arteriography, general anesthesia with intraoperative electroencephalogram monitoring, overnight intensive care unit stay, discharge on postoperative day 2) was $16,073 compared with $10,437 for a patient who completed all 5 steps of the protocol detailed above.*
Conclusions. *On the basis of these results documenting significant cost savings and acceptably low morbidity and mortality rates, this 5-step protocol may be considered the standard for performing CEA in this era of cost containment. These results may be compared with endovascular intervention, which has recently been proposed as a less expensive technique to treat carotid disease. (Surgery 1999;125:96-101.)*

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CAROTID ENDARTERECTOMY (CEA) has been proved to be effective for stroke prevention in symptomatic and asymptomatic patients with high-grade carotid stenosis.[1,2] While the indications for CEA have broadened, the cost of medical care has risen. These costs have come under intense scrutiny. Consequently, surgeons are challenged to deliver cost-effective patient care for the procedures they perform without compromising outcome, thereby maintaining acceptable morbidity and mortality rates for their operative procedures. Conventionally, CEA has been performed after contrast arteriogram,

Supported by the John F. Connolly Foundation.

Accepted for publication Aug 1, 1998.

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0039-6060/99/$8.00 + 0 **11/60/93735**

with the patient under general anesthesia with intraoperative electroencephalogram (EEG) monitoring, with mandatory admission to an intensive care unit (ICU), and with hospital discharge on postoperative day 2 or 3. We questioned whether all or some of these relatively expensive practices could be eliminated and replaced with more cost-efficient yet safe alternatives. It has been demonstrated that the implementation of well-constructed clinical pathways results in significant hospital cost savings without increased morbidity and mortality rates for vascular surgical procedures.[3] In accordance with this, we instituted a 5-step protocol for the care of patients undergoing elective CEA.

PATIENTS AND METHODS

From April 1, 1995, to December 31, 1996, all patients requiring elective CEA at Pennsylvania Hospital in Philadelphia, Pennsylvania, were entered prospectively into a 5-step protocol. Of the 141 patients requiring CEA during this time period, 109 were enrolled into this study. Of the 32 who were excluded, 9 patients were treated by vascular surgeons not participating in this protocol, 7 were treated concomitantly for other conditions (5 for coronary artery disease and 2 for brachiocephalic lesions), and 5 were admitted emergently. Risk factors and indications for surgery are listed in Tables I and II.

We attempted to fulfill all 5 steps of the protocol for each patient whenever possible. First, duplex ultrasonography (DU) of the carotid arteries was performed on all patients in our accredited vascular laboratory and was used as the sole preoperative diagnostic carotid study whenever possible. Arteriography was performed for DU findings that suspected proximal common carotid artery stenosis, outflow lesions, or borderline significant stenosis. Second, patients were admitted the day of operation whenever possible. Third, cervical block anesthesia was used instead of general anesthesia, which allowed for use of selective shunting in the awake patient and eliminated the need for intraoperative (EEG) monitoring. Fourth, each patient was observed in the recovery room for 4 hours before transfer to our dedicated vascular ward. From the recovery room, patients with cardiac or pulmonary complications, hematoma formation, neurologic changes, or hemodynamic instability requiring infusions of intravenous vasoactive medications were transferred to the surgical ICU to be monitored overnight. Patients who were stable after the 4-hour observation period in the recovery room were transferred to a dedicated vascular floor where they were placed on telemetry monitoring and were cared for by nurses specifically educated in the care of vascular surgical patients. Fifth, patients were discharged from the hospital on the first postoperative morning when appropriate, either from the vascular ward or from the surgical ICU.

Table I. Risk factors in 109 patients undergoing a 5-step protocol for CEA

Risk factor	
Average age (range) in years	70 (47-87)
Male	47 (43%)
Diabetes mellitus	28 (26%)
Hypertension	87 (80%)
Hypercholesterolemic	50 (46%)

RESULTS

One neurologic event and one death occurred in the 109 patients entered into this 5-step protocol for a combined mortality-stroke rate of 1.8% (2 of 109). A 74-year-old woman had CEA performed for hemispheric transient ischemic attacks under cervical block anesthesia with shunt placement. She suffered an intraoperative embolic stroke and was discharged with moderate upper extremity weakness. A 79-year-old woman had CEA performed for asymptomatic carotid stenosis under cervical block anesthesia. On postoperative day 1, the patient had a disruption of an external carotid artery suture line resulting in massive bleeding and return to the operating room for repair. As a result, the patient had ischemic injury to her brain and became comatose, dying on postoperative day 6. In addition, one patient experienced a postoperative myocardial infarction.

Overall, 26 (24%) of the 109 patients successfully fulfilled all 5 strategies of the protocol. Seventy-six (70%) underwent operation using DU as the sole diagnostic study. Of the 33 patients who required contrast arteriogram, 11 were for suspected inflow lesions, 10 for suspected outflow or high neck lesions, and 12 for borderline DU findings. One hundred four (95%) patients were admitted the day of operation. Five patients insisted on admission before the day of operation, primarily because of distance traveled. Eighty-three (76%) patients had cervical block anesthesia. Twenty-six patients received general anesthesia because of patient's request (10), surgeon's preference in the face of reoperative carotid surgery or communication limitations on the part of the patient (9), and conversion to general anesthesia from cervical block as a result of patient intolerance (7). Sixty-four (59%) patients were transferred to the vascular ward from the recovery room the day of operation. Reasons for ICU admission for the other 45

Table II. Indications in 109 patients undergoing a 5-step protocol for CEA

Indication	
Asymptomatic	60 (64%)
Amaurosis fugax	15 (14%)
Hemispheric TIA	11 (10%)
Nonhemispheric TIA	5 (5%)
Previous CVA	8 (7%)

TIA, Transient ischemic attack.

patients included intraoperative cerebrovascular accident (CVA) (1), hemodynamic or cardiac problems (1 with electrocardiogram changes, 2 with dysrhythmias, 15 with blood pressure control issues), wound hematoma (5, with 2 returning to the operating room for evacuation), surgeon's request (2 for previous CVA, 2 for repeat operation), patient's request (4), and bed unavailability (12). Ninety (83%) patients were discharged the first postoperative morning, 63 from the vascular ward and 27 from the ICU. The other 19 patients were not discharged the first postoperative morning because of CVA (1), cardiopulmonary problems (1 with electrocardiogram changes, 8 with blood pressure control problems), hematomas (4), and patient reluctance (5). Thirty-day readmission rate for the surviving 108 patients was 3.7% (4). One patient was readmitted with a thrombosed dialysis access graft, one with accelerated hypertension and a known history of renal artery stenosis, one with unsteady gait who was ruled out for a stroke, and one for a myocardial infarction that occurred 4 days after discharge from the hospital.

The charges for a patient having CEA performed after a contrast arteriogram, under general anesthesia with EEG monitoring, with overnight ICU stay, and with hospital discharge on postoperative day 2 was $16,073 compared with $10,437 for a patient who fulfilled this 5-step protocol at our hospital.

DISCUSSION

In a previous report in which patients received out-patient arteriograms, were admitted the day of operation, received general anesthesia, and were discharged on postoperative day 1, we showed that implementation of a vascular critical pathway for CEA decreased costs without sacrificing patient care.[4] We further modified that pathway in an effort to achieve additional cost-efficiency but again without detriment to the patient. Therefore the 5-step protocol was established after reports from our group and others who have demonstrated safety and efficacy of each aspect of the protocol. Of note, charges, rather than costs, were used because determinations of actual costs are extremely difficult.

Carotid arteriography is the gold standard for delineation of the extent of carotid arterial disease and is used by many to confirm DU findings. Many authors, however, have demonstrated the sensitivity of DU alone for evaluation of carotid arterial disease. Damson et al[5] and Redoes et al[6] evaluated 103 consecutive patients being considered for CEA who had undergone DU and cerebral angiography. They found the correlation of arteriogram with DU to be excellent, with DU alone being diagnostic and sufficient for the preoperative evaluation of carotid arterial disease in greater than 90% of patients. Arteriography changed the management in 1 patient in each of these studies. Similarly, Mattes et al[7] determined that arteriography altered management in only 3.5% of symptomatic patients and 5.7% of asymptomatic patients. In this same study only 2.4% of patients were found to have significant intrathoracic brachiocephalic lesions on arteriogram, all of which were asymptomatic and none of which required surgical correction. These results negate the argument used by advocates of preoperative arteriography who emphasize the importance of assessing the proximal arch and intracranial vessels, which cannot be visualized with DU. However, DU can suspect significant inflow and outflow stenosis, and in these cases, confirmatory arteriography should be performed. Some authors use magnetic resonance angiography instead of conventional angiography. We have been disappointed with the accuracy of magnetic resonance angiography compared with DU and conventional angiography and therefore do not use it routinely. As for safety of performing CEA without arteriography, multiple studies demonstrate the combined stroke-death rate to be only 2% to 3% when using this strategy.[8-10] These results are certainly comparable to previously established and accepted rates.[11] We strongly recommend that surgical intervention be undertaken only if DU is performed by experienced and well-trained technologists at an accredited vascular laboratory that has compared DU criteria and arteriography. Many vascular surgeons may not feel comfortable performing CEA based on DU alone because of uncertainty of the validity of the studies performed by nonaccredited laboratories. We would also point out that although only 70% (76 of 109) of patients in our series had CEA based solely on DU, the percentage has increased to closer to 90% as the surgeons and the technologists at our institution have become more comfortable with this method. As further experience is obtained, we suspect that arteriography will only be needed in 1% to 2% of cases.

Admitting patients the day of operation rather than a day or more preoperatively has contributed enormously to decreasing hospital length of stay. Because decreased length of stay is one of the factors most responsible for decreased hospital cost,[4,12] our patients were admitted the morning of operation whenever possible. Consequently, all preoperative evaluations, including DU, cardiac evaluation, and contrast arteriography, when necessary, were performed on an out-patient basis. Of note, avoidance of preoperative arteriograms and minimized use of the ICU are also responsible for significantly decreased costs. For additional cost savings, the hospital is making arrangements for patients to stay at nearby hotels at discounted rates rather than being admitted for social reasons that result in longer hospital length of stay.

Anesthesia charges may be the same whether the patient receives general or regional block anesthesia. However, we have found cervical block anesthesia to be advantageous for a number of reasons. Because we practice selective carotid shunting, regional anesthesia allows for the direct assessment of the patient's neurologic function during carotid clamping. Others who selectively shunt use intraoperative EEG monitoring under general anesthesia.[12,13] However, besides being costly, EEG has been reported to be both overly sensitive and occasionally insensitive in detecting cerebral ischemia. It has not identified all patients who required intraoperative shunts in a number of studies.[13-17] In addition, there may be more cardiopulmonary complications in patients undergoing general anesthesia.[18,19] Some authors suggest that the perioperative blood pressure may be more labile for long periods of time after general anesthesia compared with cervical block anesthesia.[20,21] Although these benefits of regional anesthesia are unfounded to a large degree, our impression of its benefits are based on our experience. In our series 12 of 15 patients admitted to the ICU for blood pressure control underwent operation under general anesthesia. These patients incurred a much larger fee for an ICU bed than if they were transferred to the vascular ward. However, as we and others have shown,[4,22] the type of anesthesia may be irrelevant concerning early discharge. Although a significant number of our patients who remained in the ICU overnight were still discharged home on postoperative day 1, a few patients needed to remain hospitalized because of persistent hypertension or hypotension. We would again point out that there is a learning curve associated with this aspect of our protocol. Although only 76% received CEA under cervical block anesthesia in this study, as the anesthesiologists became more adept at performing cervical block anesthesia and as the vascular surgeons became more comfortable with the technique, we more recently have been performing CEA using this method in approximately 90% of our patients.

We agree with others that patients can be selectively transferred to the vascular ward after a 4-hour observation period in the recovery room.[23-25] Multiple authors have demonstrated that most complications after CEA occur during this time period.[23-25] In their retrospective review of 100 patients, Morasch et al[23] found that only 16 required ICU care postoperatively. Fifteen of those 16 patients were identified in the recovery room. In addition, Hoyle et al[26] found the need for ICU admission after CEA to be low, concluding that ICU admission should be selective and can significantly decrease hospital costs. In our institution the cost of an ICU bed is $2395 compared with $1405 for a bed on the vascular ward, a difference of $990. The safety of selective ICU policy was generally supported by the fact that there were no late admissions to the ICU after our patients had been transferred to the vascular ward, although 1 patient had a massive hemorrhage the first postoperative morning. We insist that patients transferred to the vascular ward stay in a room immediately adjacent to the nurses station and have cardiac monitoring until the first postoperative morning. There were no hidden costs from this standpoint because the nurses who had previously worked on the wards were the same nurses who worked on the dedicated vascular floor and cared for these patients. It can be argued that the use of an intermediate care unit would be a more acceptable alternative to an ICU bed for a patient requiring additional monitoring. At our institution this does not affect cost because the cost of an intermediate care unit bed and an ICU bed is equivalent.

The last step of our protocol included discharge on postoperative day 1. We found this to be cost-effective because it reduced the hospital length of stay. It was also apparently safe because no patients returned to the hospital for readmission because of CEA-related problems during the first 30 days after discharge. Other authors share this view on short-stay carotid surgery.[12,27]

Endovascular intervention for the treatment of carotid arterial disease has been suggested as a less expensive technique because of shorter hospital stays and decreased overall costs.[28] We believe that proponents of endovascular treatment of carotid disease should compare their outcome and costs with the protocol proposed in this and other similar reports to represent a fair analysis.[3,4,12,22-27]

Overall, using this 5-step protocol, our combined mortality-stroke rate was within well-established and acceptable guidelines.[1,2,11] Only the patient who had a carotid hemorrhage was potentially adversely affected by this protocol, but in actuality this patient received the same expert and immediate care as if she had been in the ICU. We do not report other minor morbidities such as cranial nerve dysfunction or wound hematoma because they did not appear to directly affect the length of stay or overall costs involved. By using these comprehensive cost-cutting strategies and adhering to strict guidelines, a safe and cost-effective method of performing CEA has been preliminarily established. Although the burden of cost-efficient medicine has largely been placed on the physician, hospital and government administrators must realize that patient safety remains the primary concern of the practicing physician. Although the 5-step protocol we are proposing for CEA may appear to sacrifice patient safety solely to decrease hospital costs, we want to point out that the vast majority of our patients treated with this strategy were pleased and more than satisfied with the use of cervical block anesthesia, sleeping in a room on the vascular ward instead of in a busy ICU, and being home the day after operation. We also wish to emphasize that none of the patients were forcefully intimidated to undergo any step in the protocol. If a patient desired to remain in the ICU overnight or stay in the hospital an extra day, we gladly allowed this. Finally, if there were any particular concerns on the part of the surgeon, the protocol was abandoned. For example, patients with complex carotid disease such as recurrent stenosis or prior neck irradiation were considered on an individual basis for appropriateness for protocol inclusion. We believe that each step of this strategy is supported by many other reports in the literature and that overall, it represents a cost-efficient, but most importantly, a safe way to perform CEA. Because these are preliminary data, the number of patients successfully completing all 5 steps of the protocol is low. Clearly, there is a learning curve associated with the carotid protocol. More recent data would show increased numbers of patients completing the steps individually and therefore completing the protocol overall.

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