Carotid artery stenting with routine cerebral protection in high-risk patients

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Abstract

Background: Carotid artery stenting has emerged as an alternative treatment modality in carotid occlusive disease. This study examined our experience of carotid stenting with routine cerebral embolization protection in high-risk patients.

Methods: Clinical variables and treatment outcome of high-risk patients who underwent carotid stenting with neuroprotection were analyzed during a 26-month period.

Results: Sixty-eight high-risk patients with 72 carotid artery stenoses were treated. Procedural success was achieved in 70 cases (97%), and symptomatic lesions existed in 17 (24%) patients. Monorail Wallstents stents were used in all cases. Neuroprotective devices used were PercuSurge (28%) and Filterwire (72%). There was no periprocedural mortality or neuroprotective device–related complications. The 30-day stroke and death rate was 2.7%, and the overall complication rate was 6.9%. All stented vessels remained patent during the follow-up period (mean 15.3 ± 4.2, range 1 to 23 months). Two asymptomatic in-stent restenosis (3%) occurred at 6 and 8 months, which were both successfully treated with balloon angioplasty.

Conclusions: Our study showed that percutaneous carotid stenting with routine use of a cerebral protection device is a feasible and effective treatment in high-risk patients with carotid occlusive disease. © 2004 Excerpta Medica Inc. All rights reserved.

Keywords: Carotid artery stenting; Carotid endarterectomy; Distal protection device; High-risk patients

The efficacy of carotid endarterectomy in stroke prevention has been well proven in patients with high-grade occlusive lesions at the carotid bifurcation [1,2]. As a result, it has been considered as the standard treatment for carotid artery stenosis for nearly 3 decades. With the rapid advancement in endovascular therapy, carotid artery stenting has become a less invasive alternative to carotid endarterectomy. A recent consensus statement from the American Heart Association highlighted that carotid stenting should only be offered to limited subgroups of patients, whereas the traditional carotid endarterectomy should remain the standard treatment in patients with carotid occlusive disease [3].

Similarly, a multidisciplinary physician panel recently published a consensus statement advocating that carotid stenting should be reserved in specific subgroups of patients with carotid occlusive lesions. These patients included those with severe cardiopulmonary comorbidities or anatomic such as recurrent stenosis after previous endarterectomy, previous neck irradiation, or inaccessible lesions above the second cervical vertebrae level [4].

The perceived advantages of carotid stenting over endarterectomy are largely related to its less invasiveness because a percutaneous stenting procedure can potentially decrease the patient anxiety that is commonly associated with a surgical procedure. However, one potential complication of carotid stenting that may have impeded wide acceptance of this endovascular procedure is distal cerebral embolization. This phenomenon can occur as a result of...
Moreover, the high-risk criteria included patients with the presence of tracheostomy, history of ipsilateral neck irradiation, medical comorbidities such as those myocardial infarction, and contralateral carotid stenosis greater than 80%. The high-risk patients undergoing either carotid endarterectomy or stenting with distal cerebral protection, the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial found a significantly improved short-term perioperative stroke and death rate in the stenting group compared to the endarterectomy patients. Researchers attributed this remarkable finding to the improved stent design as well as the use of routine cerebral protection devices.

Materials and Methods

Hospital charts and clinical records were reviewed from high-risk patients who underwent carotid stenting between February 2002 and April 2004. Carotid duplex scan was performed in all patients before stenting to document the high-grade carotid stenosis. Patients with symptomatic carotid stenosis ≥60% and asymptomatic carotid stenosis ≥80% were considered for this protocol. Procedural indications, technique, and treatment outcome were examined.

Eligibility for high-risk patients undergoing carotid stenting was largely based on criteria (Table 1) established at a recent consensus conference. Briefly, they include various anatomic considerations including high carotid bifurcation (>C2 level), contralateral carotid occlusion, presence of tracheostomy, history of ipsilateral neck irradiation, previous radical neck dissection, or carotid endarterectomy. Moreover, the high-risk criteria included patients with ≥1 medical comorbidity(s) such as those myocardial infarction or stroke in the previous 3 months. High-risk pulmonary dysfunction includes patients with steroid-dependent chronic obstructive pulmonary disease or measured forced expiratory volume in 1 second <30% of predicted or <1 L/sec. Last, high-risk cardiac dysfunction includes those with left ventricular ejection fraction <30% or documented heart failure (New York Heart Association classification stage 3 or 4).

| Antithrombotic protocol |

The patient is given clopidogrel (75 mg/d) and aspirin (81 mg/d) beginning 3 days before the intervention. After the stenting procedure, clopidogrel is continued for 3 months, whereas aspirin is continued for life. Before June 2002, all patients undergoing carotid stenting received an intravenous (IV) heparin bolus (100 U/kg) to achieve systemic anticoagulation during the carotid intervention. After June 2002, the intraoperative anticoagulation regimen was changed to IV bivalirudin bolus (0.75 mg/kg) followed by an infusion rate of 2.5 mg/kg/h. At the completion of the carotid stenting, IV bivalirudin is discontinued.

Cerebral protection device

A cerebral protection device was used in all patients undergoing stenting procedures in our study. Patients received 1 of the following 2 cerebral protection devices: (1) the FilterWire EX (Boston Scientific, Natick, Massachusetts) or (2) the PercuSurge Guardwire distal occlusion balloon (Medtronic, Santa Rosa, California). The FilterWire EX device is an intra-arterial filtration deployed distal to the target carotid lesion. Using a 0.014-inch guide wire, the filter system contains a thin porous filter attached to its distal tip. The guide wire component provides support for the delivery and deployment of angioplasty balloons and stents. Once the protection system is deployed, the filter traps embolic thrombus or atheromatous debris in the distal internal carotid artery while permitting continuous antegrade blood flow. In contrast, the PercuSurge Guardwire device consists of a balloon-tipped guide wire that is inflated briefly to occlude blood flow and captures any mate-

<table>
<thead>
<tr>
<th>Table 1 High-risk criteria for patients undergoing carotid stenting (n = 72)</th>
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<td>High-risk category</td>
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</tr>
<tr>
<td>Previous neck irradiation</td>
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<tr>
<td>Previous ipsilateral carotid endarterectomy</td>
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<tr>
<td>Previous radical neck dissection</td>
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<tr>
<td>High carotid bifurcation</td>
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<tr>
<td>Tracheostomy</td>
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<td>Contralateral carotid occlusion</td>
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<td>Recent MI or stroke (within 3 months)</td>
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<td>Pulmonary dysfunction</td>
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<td>Cardiac dysfunction</td>
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MI = myocardial infarction.
rial dislodged from the wall of the vessel during carotid angioplasty or stenting procedure. Captured material is then withdrawn by using the specially designed aspiration catheter before the protection balloon is deflated and blood flow restored.

**Stenting technique**

All carotid stenting procedures were performed in the operating room with routine use of cerebral protection devices. A team consisting of two staff physicians performed the carotid stenting procedure using a mobile fluoroscopic unit (model no. OEC 9800; GE Medical System, NY, New York). An anesthesiologist was present to monitor the blood pressure as recorded by an arterial line. Oxymetry and continuous electrocardiography were similarly monitored.

An entry access was first achieved by placing a 7F introducer sheath in the femoral artery (Boston Scientific). After selective catheterization of the ipsilateral common carotid artery, the groin introducer sheath and diagnostic catheter were removed, and a 7F, 90-cm carotid guiding sheath (Boston Scientific) was placed in the distal common carotid artery by tracking over the 0.035-inch stiff Amplatz guide wire (Boston Scientific). The tracking of the guiding sheath over the guide wire in the common carotid artery was routinely facilitated by positioning the guide wire in the external carotid artery.

Selective digital carotid angiogram was performed by way of the side port of the guiding sheath to delineate the anatomy of the common, internal, and external carotid arteries. Biplanar intracranial injections were also performed to document cerebral vasculature. The Amplatz guide wire was next replaced with a 0.014-inch guide wire system with the distal embolization device, which was used to cross the carotid stenosis, was achieved in 70 (97%) of patients (24%) had symptomatic carotid artery disease. Post-stenting balloon angioplasty may be performed using either a 5-mm or 6-mm diameter angioplasty balloon depending on the appearance of the completion angiogram. Completion angiography includes biplanar carotid and cerebral views to document vascular anatomy and exclude cerebral thromboembolism. The cerebral embolization protection device was then deactivated, and the guide wire and the shuttle sheath were removed. The groin puncture site was routinely closed with a 6F femoral closure device (Perclose; Abbott Labs, North Chicago, Illinois).

**Follow-up surveillance**

A thorough neurologic evaluation was performed in the recovery room on all patients after the stenting procedure. Discharging patients home on postoperative day 1 was routine. Follow-up visit with routine carotid duplex ultrasound was performed at 1, 6, and 12 months after the intervention and each year thereafter. Primary outcome measures included any major ipsilateral stroke, other major complication, or death during hospitalization for the stenting procedure. Secondary outcome measurements included minor ipsilateral stroke and in-stent restenosis. Minor stroke was defined as a transient neurologic deficit lasting >24 hours but with no long-term residual deficit. If carotid duplex ultrasound detected a high-grade in-stent stenosis, follow-up carotid angiography with possible balloon angioplasty was performed.

**Results**

**Patient characteristics**

A total of 72 carotid stenting procedures (34 right and 38 left carotid lesions) were performed in 68 patients (65 male, overall mean age 71 years, range 56 to 82) during the study period. Detailed criteria of high-risk eligibility of these patients are listed Table 1. Patient demographic characteristics and treatment indication are listed in Table 2. Overall, 55 patients (76%) had asymptomatic stenosis, whereas 17 patients (24%) had symptomatic carotid artery disease.

**Procedural result and 30-day carotid stenting outcome**

Technical success, defined as stent placement and resolution of the carotid stenosis, was achieved in 70 (97%) of 72 arteries. Two procedures were considered technical failures because of severe common carotid artery tortuosity, which precluded safe advancement of the carotid guiding catheter. Based on our experience with these 2 patients, we have since then regarded severe carotid tortuosity as a relative contraindication for the stenting procedure. Both of

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Patient demographic characteristics and comorbidities</th>
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<tr>
<td><strong>Patient characteristics</strong></td>
<td><strong>No. of patients</strong></td>
</tr>
<tr>
<td>Total no. of patients</td>
<td>68</td>
</tr>
<tr>
<td>Age (y) (mean ± SD)</td>
<td>71 ± 8.4</td>
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<tr>
<td>Male (%)</td>
<td>65 (96)</td>
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<tr>
<td>Asymptomatic carotid lesion (%)</td>
<td>55 (76)</td>
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<tr>
<td>Symptomatic carotid lesion (%)</td>
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<tr>
<td>Stroke</td>
<td>3 (4)</td>
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<td>Transient ischemic attack</td>
<td>4 (6)</td>
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<tr>
<td>Amaurosis fugax</td>
<td>10 (14)</td>
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<tr>
<td>Comorbidities (%)</td>
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<tr>
<td>Coronary artery disease</td>
<td>53 (78)</td>
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<td>Smoking</td>
<td>43 (63)</td>
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<td>Hypertension</td>
<td>62 (91)</td>
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<td>Diabetes</td>
<td>41 (60)</td>
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<td>Chronic obstructive pulmonary disease</td>
<td>14 (20)</td>
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<tr>
<td>Hypercholesterolemia</td>
<td>37 (54)</td>
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<tr>
<td>Renal insufficiency (creatinine &gt;1.5 mg/dL)</td>
<td>13 (19)</td>
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these patients underwent successful carotid endarterectomy with uneventful recovery.

Among the remaining 70 patients in whom carotid stenting was successfully performed, the mean carotid artery stenosis was 84% ± 10%, and poststenting mean residual stenosis was 10% ± 5%. Monorail Wallstent was used in all patients. When using the cerebral protection device, the PercuSurge Guardwire device (Medtronic) was used in the initial 20 cases (28%), whereas the Filterwire system (Boston Scientific) was used in the remaining 52 cases (72%).

All cerebral protection devices were deployed successfully during the stenting procedure. Visible atheromatous debris or thrombus fragments were observed within the protection device in 43 (61%) cases. The mean procedural time of the first 30 stenting and all remaining procedures was 67 ± 14 minutes and 42 ± 10 minutes, respectively (P <0.05). The overall 30-day stroke and death rate was 2.7%. This included 1 hemispheric stroke caused by immediate carotid stent thrombosis, which was successfully treated with the Angiojet rheolytic thrombectomy [12]. One patient died from myocardial infarction 22 days after discharge. Minor stroke occurred in 2 patients (2.7%) including 1 patient with transient dysarthria and 1 patient with transient ischemic attack. Both patients had complete neurologic recovery at the time of discharge. There were no differences in the 30-day stroke and death rate between patients treated for anatomic high-risk versus cardiopulmonary high-risk criteria. Five perioperative cardiac events resulted in an overall complication rate of 6.9%. There was no difference in the overall complication rate between symptomatic and asymptomatic patients, 7.3% and 5.9%, respectively. Similarly, no significant difference in overall stroke and death rate was noted between the symptomatic and asymptomatic groups, 5.9% and 1.8%, respectively. The mean in-hospital length of stay was 1.7 ± 1.4 days.

**Poststenting follow-up**

Carotid duplex scans were performed at 1, 6, and 12 months and yearly thereafter. The mean follow-up period was 15.3 months. During this period, 6 patients (8.3%) died including 1 from a contralateral stroke, 2 from cancer, and from unknown causes. High-grade in-stent stenosis with diameter ≥80% reduction developed in 2 patients (3%) at 6 and 8 months, respectively. No neurologic symptoms occurred in any of these patients. Both patients underwent repeat balloon angioplasty of the recurrent in-stent stenosis, and both resulted in successful outcomes. These two patients remained free from neurologic symptoms without recurrent restenosis during subsequent follow-up.

**Comments**

The efficacy of carotid endarterectomy has been demonstrated in numerous clinical investigations to be superior to medical therapy alone for stroke prevention in patients with high-grade carotid stenosis [13,14]. Because of the recent rapid advancement in endovascular therapy, carotid stenting has emerged as a treatment alternative for severe carotid stenosis, with the possibility of achieving similar outcomes compared with carotid endarterectomy in patients with severe medical comorbidities [4,15]. The utility of carotid stenting has been advocated by many physicians as an acceptable alternative to endarterectomy in specific subgroups of patients such as those with postendarterectomy stenosis, radiation-induced stenosis, surgically inaccessible high lesions, contralateral carotid occlusion, or substantial cardiopulmonary morbidities [4,16–22]. Nonetheless, the debate regarding the role of stenting in both low- or high-risk patients will likely continue among many vascular surgeons. Given the constant advances in endovascular technologies, particularly related to cerebral protection devices, procedural related complications associated with carotid stenting will likely be decreased while durability in long-term follow-up is likely to be maintained [7,23,24].

In our study, a total of 68 high-risk patients underwent 72 carotid stenting procedures. The overall technical success rate was remarkable at 97%. Two stenting procedures were aborted because of severe tortuosity of the innominate and carotid artery, which precluded safe placement of the carotid guiding catheter. A cerebral embolization protection device was used in all carotid interventions. Although the PercuSurge Guardwire device was used in the initial 20 procedures, the Filterwire device became our preferred choice when it became available for clinical application in 2003. This preference was based on the theoretical advantage of the Filterwire device that permits continuous antegrade carotid flow when the device is fully deployed, which traps potential debris inside the filter. In contrast, the deployment of the PercuSurge Guardwire device is achieved by inflating an occluding balloon in the distal internal carotid artery, which might not be well tolerated in patients with compromised cerebral blood flow such as those with contralateral carotid artery occlusion.

The overall 30-day stroke and death rate in our study was 2.7%, which compares favorably with the 30-day stroke and death rates found in several other high-risk carotid stenting studies [25–28]. When we compared the overall complication rate in symptomatic and asymptomatic patients, no significant difference was demonstrated (symptomatic 7.3% vs asymptomatic 5.9%). The all-stroke-and-death analysis yielded the same result (symptomatic 5.9% vs asymptomatic 1.8%). The in-stent recurrent stenosis rate was 3% during the follow-up period, which strongly confirms that carotid stenting remains a durable procedure. All patients who developed in-stent stenosis were successfully treated with repeat balloon angioplasty. Several other large clinical studies similarly confirmed that the in-stent stenosis rate after stenting procedures, which in all cases was <5%, remained acceptable [17,29,30].

Several recent studies have demonstrated a comparable
clinical outcome with endovascular carotid intervention compared with carotid endarterectomy [9,26,31,32]. One notable report was the Carotid and Vertebral Artery Transluminal Angioplasty Study, which randomized 251 patients with high-grade carotid stenosis to balloon angioplasty and 253 cohort patients to endarterectomy [9]. The incidence of 30-day disabling stroke or death was similar between the endovascular and surgical groups, 6.4% and 5.9%, respectively. The overall stroke and death also remained similar between the 2 groups, 10.0% and 9.9%, respectively [9]. One significant finding from this study was a markedly decreased operative morbidity such as cranial nerve palsy in the endovascular groups, which occurred in 8.7% in the endarterectomy groups but in none of the endovascular group [9].

Continuous refinement in endovascular technology, particularly in the realm of carotid intervention, has prompted the development of various cerebral protection devices designed to capture embolic thrombus or atheromatous debris caused by the endoluminal therapy. As a result, this has led to several clinical investigations to evaluate the treatment outcome of distally protected carotid stenting [11,26,31–34]. Yadav et al [10,11] recently reported the early outcome of SAPPHIRE trial, which was a prospective, randomized multicenter trial of carotid endarterectomy versus stenting in high surgical-risk patients. A cerebral embolization protection device was used in all patients treated with carotid stenting. Recruiting from 29 institutions, the study enrolled 307 high-risk patients with critical carotid stenosis [11]. The study found that patients who were randomized to distally protected carotid stenting had a significantly lower rate of major events (death, stroke, or myocardial infarction) compared with patients randomized to endarterectomy, 5.8% and 12.6%, respectively. In parallel stenting and endarterectomy registries for patients who could not be randomized in the trial, 409 patients were enrolled in a stent registry. The 30-day major adverse cardiac event rate was 7.8% in the stent group compared with 14.3% in those in the endarterectomy registry [10,11].

The remarkable outcome of carotid stenting, when compared with endarterectomy in these studies, has been largely attributed to the utility of distal protection device in carotid stenting. Many researchers have similarly attested to the clinical benefit of distally protected carotid stenting compared with carotid intervention without cerebral protection. Mathias [27] reported his experience with carotid angioplasty or stenting with and without cerebral protection. In his 1026-patient series of 1222 carotid arteries treated without cerebral protection, he had a 3.5% (n = 43) stroke and death rate. In the remaining 361 patients (383 arteries) treated with protected stenting, he recorded an impressive stroke and death rate of only 1.5% (n = 6) [27]. Cremonesi et al [34] similarly reported their experience of 442 consecutive cases of carotid stenting with routine cerebral protection and had a remarkably low stroke and death rate of 1.1%. Summarizing all available literature, Kastrup et al [35] reported the results of a large meta-analysis of protected versus unprotected carotid stenting, and they concluded that there was a 3-fold higher risk of stroke and death with unprotected carotid angioplasty and stenting. Our study with routine protected carotid stenting also supports the hypothesis that cerebral protection devices are useful in decreasing stenting-related neurologic complications. Among the 70 distal protected carotid stentings in our study, visible debris were observed within the protection device in 61% of patients, which could have caused cerebral embolization or stroke.

Aside from using distal cerebral protection devices in stenting to minimize procedural-related complications, several physicians have highlighted the importance of operator’s experiences as a crucial factor in the clinical success of the carotid stenting procedure [36–38]. Ahmadi et al [36] examined their experience with unprotected carotid stenting and noted that increased neurologic complications were present in their early experience. These researchers [36] reported a combined 30-day stroke and death rate of 15% in the first 80 procedures, whereas the rate decreased to only 5% in the subsequent 240 interventions. Dietrich et al [37], who noted a 10.9% combined stroke and death rate for their first 110 carotid cases, also reported similar findings. This rate was in sharp contrast to a 6.2% rate in their subsequent 179 patients [37]. In a large multicenter survey of physicians who performed carotid stenting worldwide, which included >5,210 procedures in 4,757 patients, a similar learning curve was observed with regard to the success of the stenting procedure. In centers that performed <50 carotid stenting procedures, the combined stroke and death rate was >9%. In contrast, institutions that had performed >200 procedures had a significantly lower stroke and death, <5% [38]. Perhaps because of the routine use of a cerebral protection device in our study, we did not observe an increased stroke or death rate in patients who were enrolled in the earlier study period compared with those who were treated in the later period. Nonetheless, results of our procedural time indeed underscored the importance of the operator’s experience and procedural-related learning curve. This is evidenced by the significantly longer mean procedural time in the first 30 stentings compared with all remaining procedures, which were 67 ± 14 and 42 ± 10 minutes, respectively (P <0.05).

Admittedly, there were several limitations in our study, which included a relatively small patient sample size with limited follow-up. Moreover, all patients included in this study were based on their preoperative high-risk criteria, and the stenting treatment outcome was not based on a randomized comparison with carotid endarterectomy. The lack of randomization may raise the question of possible selection bias. Nonetheless, the low incidence of perioperative stroke and death rate in this high-risk patient group clearly underscores the potential clinical benefit of carotid stenting with cerebral embolization.

In conclusion, our study demonstrated that distally pro-
ected carotid stenting not only can be performed safely in high-risk patients but also results in durable outcome. Application of the cerebral protection device provided an added reassurance to the stenting procedure. Although results of our experience remained similar to other clinical studies that underscored the clinical benefit of carotid stenting, long-term stent patency and clinical outcome are clearly needed. At present, carotid stenting with cerebral protection in subsets of patients with high-risk criteria remains appropriate until more clinical evidence becomes available from larger prospective randomized trials [4].

References

Discussion

John Edit, M.D. (Little Rock, AR): “All high-risk diabetic patients should have stenting, not surgery.” So says Dr. Mark Willy, an interventional radiologist at the University of Texas in San Antonio. In an article presented on the Society of Interventional Radiology Web site, he goes on to say that patients can go home the next day, there is no general anesthesia, there is no infection rate, and the interventional procedure takes only 20 or 30 minutes. One can only conclude that carotid endarterectomy is an archaic procedure and should be abandoned in favor of percutaneous treatments. This conclusion is based on a review of the available literature, which in reality consists almost entirely of registry data entered voluntarily by motivated participants or a single-center case series and 2 widely publicized randomized trials. One of these trials, CAVITAS, took place before the widespread use of stents and so-called cerebral protection devices. The other large randomized trial, nicknamed SAPPHIRE to which Dr. Lin referred involves high-risk patients, but it demonstrated a benefit for carotid stenting versus endarterectomy owing chiefly to a decrease in the risk of non-Q–wave myocardial infarction in the angioplasty group rather than a dramatic decrease in the risk of stroke. I should also point out that carotid stenting is still not yet recognized by the Centers for Medicare and Medicaid Services as a reimbursable procedure, although that is expected to change in January 2005, or at least the people who are participating in stenting are hoping that in true. At the outset, let me say that Dr. Lin and his partners have done a remarkable job of putting Baylor and Houston on the endovascular map in a short time. They have identified 68 high-risk patients whose indications for treatment of 72 carotid artery lesions (76%) were asymptomatic. There were 2 technical failures, 1 major stroke, 2 minor strokes, 1 death from myocardial infarction and either 4 or 5 additional adverse cardiac events with an overall 30-day stroke and death rate that was a commendable 2.7%. It should be remembered again that the majority of patients with asymptomatic carotid stenosis never have a stroke despite their treatment. In the present series, most procedures were undertaken for either the complete absence of symptoms or for the presence of transient monocular blindness alone, which carries a substantially decreased risk of eventual stroke. Thus, the investigators have wisely selected a population of patients who were likely to do well regardless of the treatment. I also want to address the concept of the so-called high-risk endarterectomy patient. Patients are classified as high-risk based on either medical comorbidities or anatomic issues such as previous neck surgery, neck irradiation, or high bifurcations. There have been several reports in the past 2 or 3 years from across the country where surgeons have looked retrospectively at the results of their carotid endarterectomy procedures and identified patients who would have been high risk had they classified them on the original go around. In our patients, this is approximately 25%. We and others have not observed a significant difference in results in these so-called high-risk patients, especially with the use of local anesthetic, as you can just see from the previous presentation. So, my first question is this: During the same time period that you collected data on this series of stent patients, did you perform carotid endarterectomy on patients who could be considered high risk according to your high-risk criteria, and if so, how did they do? Another issue is how you chose the contraindications to stenting. You had a lot of different recommendations, but with the results that you had, it is difficult to see how you came to those recommendations. For example, do you use ultrasound to divide patients into those who have more friable plaques, which are more likely to embolize, compared with plaques that are more stable and thus less likely to embolize? And the third issue relates to the so-called cerebral protection devices. There are no large randomized trials comparing cerebral protection devices with stenting without protection. Although it would seem intuitive that cerebral protection devices are beneficial, it is important to remember that the protection device itself must be passed through the stenotic lesion without protection. There have been numerous reports of significant complications related to their use including dissection and rupture of the internal carotid artery, thrombosis, induction of spasm, and mechanical failure. Therefore, I think the jury is still out on the benefit of cerebral protection. We have had 1 patient in whom we could not unsheathe one of the filter wires in a tortuous carotid artery. We have abandoned the use of the protection device and proceeded with unprotected stenting. Did you have any problems with cerebral protection devices that we can learn from?

Answer

Peter Lin, M.D. (Houston, TX): Regarding your first question of high-risk anatomic or physiologic criteria, we do consider certain criteria as absolute indications, in contrast to other relative indications, for carotid stenting in these high-risk patients. These distinctions can also be grouped based on either physiologic or anatomic considerations. For example, we considered patients with a history of radical neck dissection, neck irradiation, or tracheostomy as having absolute or anatomic criteria for the stenting procedure in terms of high-risk eligibility. In contrast, with regards to physiologic criteria, such conditions as severe chronic obstructive pulmonary disease—as defined by certain pulmonary function tests—or a recent myocardial infarction with documented low ejection fraction would be considered relative high-risk physiological indications. For
those patients who had absolute high-risk indications, we would only offer the treatment option of carotid stenting under this protocol. In contrast, for those who had relative physiologic indications, we would offer the option of either carotid stenting or carotid endarterectomy. However, I can tell you that based on our experience, if you offer patients both options, almost all of them will choose the less-invasive option, i.e., percutaneous, compared with the surgical option, which leaves a scar in the neck. With regard to the high-risk patients who were offered both treatment options, we observed differences in treatment outcome between carotid stenting and carotid endarterectomy. Those high-risk patients who underwent carotid endarterectomy, which is performed with the patient under general anesthesia, had poorer outcomes compared with those undergoing carotid stenting, which is routinely performed with the patient under local anesthesia. Your second question deals with ultrasound. I do not have an answer right now regarding the ultrasound criteria to determine anatomic contraindications for carotid stenting. In our series, every patient who underwent preoperative ultrasound also received a preoperative angiogram, and by the angiographic results that we determine if a patient has suitable anatomy to undergo the carotid stenting procedure. Regarding the last question about the cerebral protection device, we routinely examine the debris after every procedure, and we have observed that in >50% of cases, macroscopic debris could be identified within the filter device. It is our opinion that the distal protection filter does provide added protection as well as added safety to the procedures.

**Question**

**Richard Pennell, M.D.** (St. Louis, MO): Do you perform the carotid angiogram and the carotid stent on the same day, or do you have the patient come back for the carotid intervention at a later date?

**Answer**

**Peter Lin, M.D.** (Houston, TX): Because the carotid stenting procedure in this series was performed under a high-risk clinical protocol, we do not perform concurrent procedures. For this high-risk clinical protocol, we would perform a diagnostic angiogram and then have a detailed discussion with the family and the patient regarding the treatment options as well as benefits and risks of the procedure. For those with relative inclusion criteria for the procedure, we would offer the possibility of either stenting or endarterectomy, and then each patient can choose his or her treatment option.
**Question**

Ronald Stewart, M.D. (San Antonio, TX): I would add that the SAPPHIRE data is >1 year old now. The 1-year data hold up the same as the 30-day data. I have heard Ken Oriel go through this. It was performed at the Cleveland Clinic and it involves many surgeons. The defense is that these results are not that different from what is in the published data. Again, the big difference in this composite end point was that they had many non–Q-wave myocardial infarctions, but even at the stroke level the stenting was comparable with or better than carotid endarterectomy. Are there plans to do a National Institutes of Health–sponsored or big national non–industry-sponsored randomized clinical trial? As a nonvascular surgeon, it is hard for me to imagine that putting in a balloon and dragging that thing through the lesion and then blowing a balloon up with the little net is actually going to result in a stroke rate equivalent to the stroke rate from an elegant operation done by a well-trained surgeon.

**Answer**

Peter Lin, M.D. (Houston, TX): Just remember, it was not too long ago that somebody proposed making 4 little incisions in the abdomen and removing the gallbladder using laparoscopic instruments. This less invasive-surgical option has become the standard of the treatment compared with the open surgical choice. I believe that the benefits of the carotid stenting procedure are real. Further issues regarding reimbursement will be sorted out in the near future. The technology and physician skills will improve, and this durability of the stenting procedure will likely surpass the surgical treatment in the future.