Procedural Safety and Short-Term Outcome of Ambulatory Carotid Stenting

Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Gishel New, MD; Sriram S. Iyer, MD

Background and Purpose—Ambulatory procedures increase patient comfort and enhance cost-effectiveness. We sought to determine the feasibility and safety of ambulatory carotid stenting.

Methods—A selected group of patients was admitted and discharged the same day after the carotid stenting procedure. Immediate and short-term outcomes are reported.

Results—A total of 98 ambulatory carotid stenting procedures (98 hemispheres in 92 patients) were performed. There were 66 men (72%), and the mean age was 70.6 years. Of the patients, 28% had neurological symptoms related to the treated artery within 3 months before the procedure. Sixteen percent of the patients had prior carotid endarterectomy, 4% had prior ipsilateral neck radiation, and 8% had complete occlusion of the contralateral internal carotid artery. Successful access site hemostasis was ensured in all patients with suture-mediated vascular closure devices in 96 (98%) and manual compression in 2. Clinical follow-up was available for 96% of the patients at a mean time of 6.6 months. There were no neurological events, deaths, repeated procedures, or major access site complications.

Conclusions—Ambulatory carotid stenting is both safe and feasible. This approach will enhance the applicability of the procedure by increasing patient comfort and potentially reducing procedural costs. (Stroke. 2001;32:2305-2309.)

Key Words: carotid arteries ■ outcome assessment ■ stents

Economic constraints and advances in endovascular techniques have led to an increasing trend toward a less invasive approach for the treatment of peripheral vascular disease.1–5 Aimed at improving patient comfort and minimizing hospital costs without compromising procedural safety, a growing number of endovascular procedures are being performed successfully in the ambulatory setting with acceptable short-term outcomes.1–5 Elective carotid stenting has emerged as a less invasive endovascular alternative to carotid endarterectomy for the treatment of occlusive carotid artery disease, and accumulating evidence suggests a favorable efficacy in preventing stroke.6–8 The procedure is increasingly applied to treat high-risk surgical populations, and randomized trials are being undertaken to compare its safety and efficacy with that of carotid endarterectomy in low-surgical-risk patients. The demonstration of carotid stenting as a stroke prevention therapy that can be performed safely in the ambulatory setting will enhance its application. In this study, we report the procedural safety and short-term outcome of ambulatory carotid stenting in a selected group of patients undergoing the procedure.

Subjects and Methods

Study Population
Between April 1999 and January 2001, 341 carotid stenting procedures in 300 patients were performed at our institution. Of these, 98 (29%) were performed in the ambulatory setting (Figure). All procedures were performed according to a protocol investigating the outcome of carotid stenting in patients with extracranial carotid artery stenoses (diameter obstruction, symptomatic ≥60% and asymptomatic ≥80% by North American Symptomatic Carotid Endarterectomy Trial angiographic methodology). Our enrollment criteria have been published elsewhere.6

Ambulatory Setting
Patients were electively admitted from home on the morning of the procedure in the fasting state through a same-day admission unit, having had clopidogrel (Plavix, Pfizer Inc) 75 mg once a day and aspirin 325 mg twice a day for a minimum of 7 days before admission. Alternatively, patients received a minimum of 650 mg aspirin and 450 mg clopidogrel within the 24 hours before the procedure. All patients had a prior duplex ultrasound or magnetic resonance angiographic study indicating severe carotid artery stenosis. Complete cerebral angiography was then performed in the angiography suite with subsequent carotid stenting. All procedures

See Editorial Comment, page 2308
were performed in patients in the conscious state without general anesthesia or sedation. The vascular access site was sealed at the end of the intervention with a suture-mediated closure device (Closure, Perclose Inc). After the procedure, patients were observed in an interventional care unit for ≈6 hours. Patients were advised on the possibility of same-day discharge but were made aware that the final decision is based on the clinical condition and successful access site homeostasis at the end of the observation period. All patients had neurological evaluation before intervention and before discharge. This evaluation included clinical history, complete neurological examination, and a National Institutes of Health Stroke Scale assessment.

Patients were discharged home on the same day as the procedure only if they (1) had successful carotid stenting with no neurological events during the procedure or the postprocedural observational period (a minimum of 4 hours), (2) achieved successful hemostasis of the arteriotomy site and ambulated at a level commensurate with their anticipated activity at home without complications, (3) understood the discharge instructions and were expected to be compliant, and (4) had adequate care at home by a person well informed of the potential complications who could provide basic medical support and obtain immediate medical care. Patient compliance was assessed through a direct interview with the patient and family. All patients were given written discharge instructions that emphasized the potential complications and immediate care and included emergency telephone numbers.

Extended hospitalization was required in remaining carotid stenting cohort for the following reasons: (1) patients required hospitalization for management of a nonrelated medical problem; (2) patients had manual compression hemostasis and required prolonged bed rest; (3) patients developed complications that required in-hospital care; (4) the procedure was performed late in the day when early discharge was inconvenient for the patient or the family; (5) patients were enrolled in a study protocol that required prolonged hospitalization; or (6) there was inadequate support at home.

Follow-Up
Follow-up was conducted by dedicated research coordinators through a telephone interview or directly by a physician at 30 days, 6 months, and 1 year. Follow-up data were recorded on a standard form and entered into a computerized database. The form included specific questions regarding potential neurological and vascular access site complications. Early in the series, patients received a follow-up telephone call 1 day after discharge. This was carried out on 44 patients (46%). Short-term follow-up was completed on 96% of the patients at a mean of 6±4 months.

Procedural Protocol
Written informed consent was obtained in all patients before the procedures. Vascular access was gained via the femoral artery. All carotid stenting procedures were performed through a 6F or 7F 80-cm-long sheath (Shuttle, Cook Inc) with the standard technique previously described.9 Self-expanding stents were used (Wallstent, Boston Scientific; SMART, Cordis Inc; and others). At the completion of the procedure, a limited ipsilateral iliofemoral angiography was performed to determine suitability for the vascular closure device. The vascular closure device (Closure, Perclose Inc) was then applied according to the manufacturer instructions as previously described.10 When a 7F Shuttle sheath was used (SMART stent requires a 7F sheath), the closure sutures were deployed before sheath insertion to minimize arteriotomy size but were knotted after the intervention. Clopidogrel (Plavix, Pfizer Inc) 75 mg once a day and aspirin 325 mg twice a day were continued for 4 weeks. Aspirin 325 mg once a day was then continued indefinitely.

Definitions
For an ambulatory procedure, the patient was admitted and discharged on the same day as the intervention without an overnight hospital stay. Extended hospitalization occurred when the patient required a minimum of 1 overnight hospitalization. A successful hemostasis was the absence of access site complications after ambulation at a level commensurate with patient’s anticipated activity at home. Vascular access site complications included localized hematoma, bleeding requiring blood transfusion, late bleeding, vascular injuries (pseudoaneurysm, AV fistula), or access site infection. Late bleeding was defined as any bleeding regardless of severity that occurred after the original hemostasis was achieved.

Statistical Analysis
All values are expressed as mean±SD. Clinical characteristics were compared by use of the χ² test for categorical variables and Student’s t test for continuous variables.

Results
The Table summarizes the clinical characteristics of the ambulatory and the hospitalized patients. A total of 98 successful ambulatory carotid stenting procedures were performed on 92 patients (98 carotid arteries). There were 66 men (72%) and 26 women (28%). Their mean age was 70±9 years. Twenty-eight percent of the patients had neurological symptoms related to the treated artery within 3 months before the procedure. The remaining patients were asymptomatic. Complete brachiocephalic angiography was performed during the same setting in 92 procedures. Six patients had staged bilateral carotid stenting performed on different occasions.
Immediate Outcome

All patients had technically successful procedures using distal balloon protection (GuardWire, Percusurge) in 23%. The mean percent diameter stenosis was reduced from 78±9% to 11±14%. A single bolus of glycoprotein IIb/IIIa antagonists (Aggrastat, Pfizer Inc) was administered in 3 patients (3%). Successful hemostasis was ensured after all procedures with vascular closure devices in 96 patients (98%). The remaining 2 patients failed the vascular closure, and subsequent hemostasis was successfully achieved by manual compression. Two patients developed visual disturbances during the intervention that resolved within 30 minutes. No neurological events occurred during the procedure or the observation period in the remaining patients. Transient bradycardia and transient hypotension occurred during 38% and 14% of the procedures, respectively, but no sustained hemodynamic instabilities were observed in any of the patients.

Follow-Up Results

One patient developed fever and vomiting 1 day after discharge that was attributed to a viral infection. There was no evidence of infection or bleeding at the vascular access site. A second patient who had a suture-mediated vascular sealing developed serious focal discharge from the access site at 6 weeks. No evidence of infection or bleeding was noted at the site, and he improved with conservative management. The remaining patients were asymptomatic. There have been no neurological events, deaths, access site complications, or repeated procedures.

Discussion

This study demonstrates that after carotid stenting, a group of patients at low risk for postprocedural complications can be reliably identified and safely discharged home on the same day. Essential for the early discharge selection are the logistics of scheduling and the need for neurological testing and assessment, approximately half of the procedures were scheduled in the afternoon, and an evening discharge was not convenient for the patient or the family. Additionally, a significant portion of the patients had manual compression hemostasis either because they did not have suitable anatomy for a vascular closure or because the operator chose not to use a closure device and therefore were ineligible for the early discharge.

Until recently, prolonged bedrest and overnight hospitalization have been the general practice after transfemoral endovascular procedures. The advent of the vascular closure devices has allowed early ambulation and discharge after endovascular procedures in select patients10 –12. In this series, only 1 type of closure devices (Closure, Perclose Inc) was used. It is possible, however, that comparable results could have been achieved with other closure devices or traditional methods of manual compression homeostasis. Successful application of these devices in our series was enhanced by the predominant use of 6F sheaths, low heparin dosing, and infrequent use of glycoprotein IIb/IIIa antagonists.

Two theoretical concerns exist in discharging patients early after carotid stenting: potential neurological events and the risk of vascular access site complications. After the first case report of ambulatory carotid stenting, these concerns were expressed. It was argued that the procedure is still at an early investigational stage and that mandatory prolonged in-hospital observation is necessary.12,13 During the early phase of the carotid investigation, we hospitalized the patients for 2 to 3 days to observe them for complications. The low frequency of postprocedural events encouraged us to consider the ambulatory setting approach. The low incidence of embolic neurological complications has been widely documented.6–8 Wholey et al7 reported a multicenter experience with >5200 cases of carotid stenting that included the learning curve of the operators. The combined all-strokes and death rate in that report was 5%, including 2.7% minor strokes, 1.5% major stroke, and 0.8% deaths. In our experience, most neurological events occurred within 2 hours of the procedure, mostly during the intervention, and events were extremely rare after 4 hours or within 30 days of discharge. In contrast to coronary interventions, the risk of acute stent thrombosis of the treated carotid artery is very rare, provided that appropriate oral antiplatelet agents are administered

---

Patient Clinical Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Ambulatory Group (n=92) (Hemispheres=96)</th>
<th>Hospitalized Group (n=208) (Hemispheres=243)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean±SD), y</td>
<td>70±9</td>
<td>72±9</td>
<td>NS</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>66 (72)</td>
<td>132 (63)</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>75 (81)</td>
<td>183 (88)</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>21 (23)</td>
<td>75 (36)</td>
<td>0.004</td>
</tr>
<tr>
<td>Hyperlipidemia, n (%)</td>
<td>76 (83)</td>
<td>162 (78)</td>
<td>NS</td>
</tr>
<tr>
<td>Coronary artery disease, n (%)</td>
<td>56 (56)</td>
<td>129 (62)</td>
<td>NS</td>
</tr>
<tr>
<td>Prior CEA, n (%)</td>
<td>15 (16)</td>
<td>29 (14)</td>
<td>NS</td>
</tr>
<tr>
<td>Prior neck radiation, n (%)</td>
<td>4 (4)</td>
<td>12 (6)</td>
<td>NS</td>
</tr>
<tr>
<td>Contralateral occlusion, n (%)</td>
<td>8 (8)</td>
<td>17 (8)</td>
<td>NS</td>
</tr>
</tbody>
</table>

CEA indicates carotid endarterectomy.
before the intervention.\textsuperscript{6–8} This report clearly supports the fact that in experienced centers, the procedure has passed the early investigational stage and prolonged hospitalization appears to be no longer necessary.

It is important to emphasize that in this study all patients and families participated in an extensive discussion with the attending physician concerning the various therapeutic options for the treatment of carotid stenosis before the procedure, including medical, surgical, and endovascular therapies. During the discussion, all risks and benefits of each treatment were carefully explained. We pointed out that the carotid endarterectomy is the standard therapy and that carotid stenting, pending the results of randomized trials, is considered an investigational, less invasive alternative.

An important advantage of the endovascular treatment is the safe combination of multiple diagnostic or interventional procedures during the same setting. It improves patient comfort, and by decreasing the number of procedures and hospitalizations, it enhances the cost-effectiveness.\textsuperscript{14} In this series, cerebral angiography was performed during the same setting in all patients. In undertaking this approach, we informed our patients that the procedure consists of a diagnostic and an interventional component. The risks and benefits of both components are explained before the procedure was begun, and patients signed a detailed protocol consent form. The treatment decision was made after the diagnostic angiography was completed, depending on lesion severity and suitability of the vascular anatomy for carotid stenting. The procedure was terminated after the diagnostic component if the stenosis measurement showed a less severe lesion or the lesion anatomy was unsuitable for stenting.

In conclusion, this series demonstrates that in experienced centers carotid stenting can be undertaken in the ambulatory setting with satisfactory immediate and short-term outcomes.

Carotid angioplasty and stenting (CAS) is rapidly gaining popularity as an alternative to carotid endarterectomy (CEA) for the treatment of carotid bifurcation stenosis. Many reports have established the safety and efficacy of CAS \textsuperscript{1–3} and the first of several randomized, controlled trials comparing CAS to CEA, the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS), has reported essentially identical success and complication rates for the respective procedures.\textsuperscript{4} The definitive North American trial, the Carotid Revascularization Endarterectomy vs Stent Trial (CREST), has recently begun randomizing patients.\textsuperscript{5,6}

Al-Mubarak et al have lowered the threshold for considering CAS as an alternative to CEA by demonstrating the feasibility and safety of performing CAS as an ambulatory, outpatient procedure. Expanding on their initial case report,\textsuperscript{7} they have shown that in a subset of their patient population (98 of 341 procedures, or 29\%), both diagnostic and therapeutic procedures can be safely performed as 1-day-care, outpatient procedures, thus eliminating the expense of hospitalization. The patients were carefully selected and were only discharged home on the same day as the procedure if (1) there were no neurological events during or up to 4 hours after the procedure, (2) successful hemostasis was achieved at the femoral arteriotomy site and the patients were able to ambulate appropriately, (3) patients were adequately compliant and understood the postprocedural instructions, and (4) adequate home care was available, with immediate access to emergency care if necessary.

None of the patients showed any neurological deficit during the procedure or in the subsequent 4 hours. One patient developed a minor infection at the arteriotomy site 6 weeks after CAS, but no other complications were observed in follow-up to a maximum of 1 year. Concerns that complications and minor neurological events may be missed by an early discharge have therefore been addressed. Clearly, a procedure once limited to symptomatic patients with contraindications to CEA can now be performed in outpatients, many of whom are asymptomatic. But should it be done this way?

\textbf{References}

A major stimulus for performing procedures on an outpatient basis is the perceived cost savings by eliminating hospitalization. In this series, key elements that allowed early discharge were the use of a femoral arteriotomy closure device (Closure, Perclose Inc) to facilitate early hemostasis and a distal balloon protection device (GuardWire, Percusurge) to minimize embolic complications. Both of these devices are expensive, initially complicated to use, and unvalidated by clinical trials. A cost analysis between their outpatient group and uncomplicated CAS patients who spent a night in hospital would have been interesting.

There is a risk that CAS may be perceived as a simple outpatient procedure, attracting less experienced operators than the authors of this paper, unfamiliar with the complexities and risks of carotid atherosclerosis treatment. The facts that 72% of the study group were asymptomatic, and that a large percentage may not have had hard contraindications to CEA, also invites potential abuse. The decision to proceed with CAS after diagnostic angiography was often made in the angiography suite in unanesthetized patients. In a less-well-prepared patient population, the potential to proceed with CAS as a simple “add-on” to cerebral angiography is obvious. Hospitalization was still required for a variety of reasons in 71% of the patients in this study, indicating that for the majority of CAS candidates, same-day discharge is not yet appropriate.

The goals of carotid disease treatment must remain clear—safety and effectiveness. Postprocedure length of stay is important and cost reduction is laudable, but these factors must not become the major end points of outcome analysis. CEA remains the only scientifically validated procedure for the treatment of symptomatic carotid stenosis, and until CAS has been validated in a similar way, the results of this study must be viewed with caution.

### References


Procedural Safety and Short-Term Outcome of Ambulatory Carotid Stenting
Nadim Al-Mubarak, Gary S. Roubin, Jiri J. Vitek, Gishel New and Sriram S. Iyer

*Stroke*. 2001;32:2305-2309
doi: 10.1161/hs1001.096005

*Stroke* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2001 American Heart Association, Inc. All rights reserved.
Print ISSN: 0039-2499. Online ISSN: 1524-4628

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://stroke.ahajournals.org/content/32/10/2305

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in *Stroke* can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to *Stroke* is online at:
http://stroke.ahajournals.org/subscriptions/