Transcervical carotid stenting with internal carotid artery flow reversal: Feasibility and preliminary results

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Objective: **Transfemoral carotid artery stenting (CAS), with or without distal protection, is associated with risk for cerebral and peripheral embolism and access site complications. To establish cerebral protection before crossing the carotid lesion and to avert transfemoral access complications, the present study was undertaken to evaluate a transcervical approach for CAS with carotid flow reversal for cerebral protection.**

Methods: **Fifty patients underwent CAS through a transcervical approach. All patients with symptoms had greater than 60% internal carotid artery (ICA) stenosis, and all patients without symptoms had greater than 80% ICA stenosis. Twenty-one patients (42%) had symptomatic disease or ipsilateral stroke, and 8 patients (16%) had contralateral stroke. Four patients (8%) had recurrent stenosis, 7 patients (14%) had contralateral ICA occlusion, and 1 patient (2%) had undergone previous neck radiation. Twenty-seven procedures (54%) were performed with local anesthesia, and 23 (46%) with general anesthesia. Using a cervical cutdown, flow was reversed in the ICA by occluding the common carotid artery and establishing a carotid–jugular vein fistula. Pre-dilation was selective, and 8-mm to 10-mm self-expanding stents were deployed and post-dilated with 5-mm to 6-mm balloons in all cases.**

Results: **The procedure was technically successful in all patients, without significant residual stenoses. No strokes or deaths occurred. There was 1 wound complication (2%). All patients were discharged within 2 days of surgery. Mean flow reversal time was 21.4 minutes (range, 9-50 minutes). Carotid flow reversal was not tolerated in 2 patients (4%). Early in the experience, carotid flow reversal was not possible in 1 patient, and there were 1 major and 3 minor common carotid artery dissections, which resolved after stent placement. One intraoperative transient ischemic attack (2%) occurred in 1 patient in whom carotid flow was not reversed, and 1 patient with a contralateral ICA occlusion had a contralateral transient ischemic attack. At 1 to 12 months of follow-up, all patients remained asymptomatic, and all but 1 stent remained patent.**

Conclusion: **Transcervical CAS with carotid flow reversal is feasible and safe. It can be done with the patient under local anesthesia, averts the complications of the transfemoral approach, and eliminates the increased complexity and cost of cerebral protection devices. Transcervical CAS is feasible when the transfemoral route is impossible or contraindicated, and may be the procedure of choice in a subset of patients in whom carotid stenting is indicated. (J Vasc Surg 2004;40: 476-83.)**

The beneficial effect of cerebral protection during carotid artery stenting (CAS) has not been proved in controlled, prospective trials. It is well established, however, that cerebral embolization is a common event that occurs almost universally during all technical steps of CAS[1,2] and that a large number of microembolic signals are detected with transcranial Doppler scanning during CAS.[3] Embolic protection during CAS has not been universally accepted, because of the relatively low incidence of clinically apparent stroke during CAS and lack of correlation of embolic signals with clinically significant neurologic events. However, a meta-analysis of multiple institutional experiences has suggested that cerebral protection during CAS may be associated with reduction in the incidence of cerebral embolization and neurologic complications.[4] The Safety Committee of the European Endarterectomy Versus Angioplasty in Patients With Symptomatic Severe Carotid Stenosis trial, which compared CAS with or without cerebral protection with carotid surgery in patients with recently symptomatic, severe carotid artery stenosis, has recently recommended limiting the trial to patients with protection during CAS, because of a 3.9-fold higher incidence of stroke in CAS without protection.[5] Although the data are not based on a randomized comparison of unprotected versus protected CAS, they suggest that cerebral protection during CAS reduces the incidence of stroke.

This evidence reinforces the preexisting consensus on the advisability of the use of cerebral protection during CAS.[6] Currently available cerebral protection devices, however, provide incomplete protection, and their use adds significantly to the complexity, duration, and cost of CAS.[7] Distal protection devices (DPDs) currently under clinical

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evaluation are particularly fraught with technical limitations and potential complications.[8] Distal balloon occlusion devices reduce only partially the incidence of periprocedural embolization during CAS,[9,10] and distal filtering devices fail to capture a significant number of embolic particles released during CAS both in vitro[11] and in vivo.[12,13] In addition, all distal protection systems require crossing the carotid lesion before protection is in place, arguably one of the most emboligenic maneuvers during CAS.

Cerebral protection with proximal common carotid artery (CCA) occlusion and internal carotid artery (ICA) flow reversal suppresses cerebral embolization in vitro,[14] and produces a negligible incidence of periprocedural neuroembolic complications in vivo.[15,16] The transfemoral approach for CAS, with or without protection, is associated with a small but definite risk for cerebral and peripheral embolization secondary to arch and proximal supra-aortic trunk instrumentation, and groin complications. In addition, the transfemoral route may not be feasible in patients with severe aortoiliac occlusive disease or in patients with unfavorable anatomy.

To incorporate the advantages of cerebral protection with ICA flow reversal and to eliminate the potential complications, increased technical complexity, and additional cost of transfemoral protection devices, we developed a technique that uses a transcervical approach with ICA flow reversal.[17] The purpose of the present study was to evaluate the results of this technique in our first 50 patients.

METHODS

Patients. From March 2003 to March 2004, 50 consecutive patients underwent transcervical CAS. Ten of these patients were part of a separate prospective study to evaluate changes in cerebral venous oxygen saturation during transcervical CAS, and are the base of another report.[18] Data were prospectively collected regarding medical history, comorbid conditions, symptomatic status, degree of carotid stenosis, intraoperative findings and events, and postoperative follow-up.

Patient mean age was 71.6 years (range, 57-84 years). Forty-two patients (84%) were men. Associated medical comorbid conditions are summarized in the Table. The indications for CAS were high cardiac risk in 22 patients, in 10 of them before coronary revascularization, severe chronic obstructive pulmonary disease in 3 patients, recurrent carotid stenosis after endarterectomy in 4 patients, high bifurcation in 4 patients, high ICA lesion in 3 patients, unfavorable neck anatomy in 2 patients, and neck radiation in 1 patient. In 11 cases the decision was made by surgeon and patient consensus, after all treatment alternatives had been presented to the patients. Informed consent of the off-label use of stents was obtained from all patients. The procedures were conducted at national health care systems where no third parties were billed for hospital or physician services.

Twenty-one patients (42%) had symptomatic carotid artery stenosis, 14 with hemispheric transient ischemic attack (TIA), 1 with amaurosis fugax, and 6 with a previous ipsilateral hemispheric stroke. In addition, 8 patients (16%) had previous contralateral hemispheric stroke. Seven patients had occlusion of the contralateral ICA, and 2 patients had occlusion of the ipsilateral external carotid artery (ECA). Four patients had recurrent ICA stenosis after carotid endarterectomy, and in 2 patients the lesion was located in the distal ICA and deemed too high for safe surgical access. The treated carotid artery was the right in 29 patients (58%), the left in 19 patients (38%), and both in 1 patient (2%).

Medical comorbid conditions in 50 patients undergoing transcervical carotid artery surgery

Medical comorbid condition	n	%
Hypertension	42	84
Hypercholesterolemia	25	50
Severe coronary artery disease	28	56
Smoking	16	32
Diabetes mellitus	11	22
Severe chronic obstructive pulmonary disease	3	6

The degree of carotid artery stenosis was estimated preoperatively with duplex ultrasound scanning in all patients. Preoperative carotid angiography was performed in 27 patients (54%). North American Symptomatic Carotid Endarterectomy Trial criteria were used to assess the angiographic degree of stenosis. Intraoperative anteriography with portable fluoroscopy confirmed the degree of carotid stenosis in all patients.

Transcervical CAS protocol and technique. All patients received aspirin, 325 mg/day, and clopidogrel, 75 mg once a day, for at least 4 days, or 300 mg/day for 2 days before the procedure. Twenty-seven procedures (54%) were performed with local anesthesia, mostly in patients at high cardiac risk, and 23 procedures (46%) were performed with general anesthesia in patients without cardiac contraindications. Two procedures were initiated with local anesthesia and converted to general anesthesia because of patient discomfort. No sedation was given before or during the procedure in patients under local anesthesia. One hundred units of heparin per kilogram of body weight was given intravenously before carotid puncture. Intra-arterial blood pressure and transcutaneous oxygen saturation were continuously monitored in all patients. In procedures performed in patients under local anesthesia, neurologic status was assessed at regular intervals by the anesthesiologist and surgeon.

A description of our surgical technique for transcervical carotid angioplasty and stenting has been published.[17] The technique consists of accessing the CCA through a vertical mini-incision (4 cm) at the base of the neck, controlling the proximal CCA with a Rummel loop, and establishing an arteriovenous fistula between the CCA and the internal jugular vein by placing 8F × 11-cm introducer sheaths (Super Arrow Flex percutaneous introducer sheath; Arrow International) in these vessels and connecting the introducers with a short (15 cm) segment of tubing. After occluding

the CCA with the Rummel loop and establishing a carotid artery–jugular vein fistula, retrograde flow in the ICA is ascertained with fluoroscopy by injecting a small amount of contrast in the CCA and immediately opening the fistula, observing contrast flow from the ICA into the internal jugular vein.

The first 6 CAS procedures were performed with 2 separate introducer sheaths in the CCA, 1 (5F) to occlude the external with a 4-mm balloon and connect to the jugular vein fistula, and a second 5F introducer sheath to conduct the intervention. The last 44 procedures were performed with a single CCA 8F introducer sheath. ECA flow was occluded with a separate 4-mm balloon in the first 22 procedures. The last 28 procedures were performed without ECA occlusion, with angiographic demonstration of ICA flow reversal in all cases. Using hand injection, digital angiography was performed in the lateral and oblique planes to localize and quantitate the degree of ICA stenosis. With flow reversal in place, a 0.014-inch guide wire (Platinum Plus, ST, 0.014-180 cm; Boston Scientific) in a 4F × 40-cm long Berenstein catheter (Angiodynamics) was introduced through the CCA sheath for selective crossing of the ICA stenosis. The tip of the guide wire was advanced to a position just proximal to the carotid siphon.

Predilation of the lesion was performed in 28 patients with balloons 3 or 4 mm in diameter. Self-expandable stents 10 × 24 mm, 10 × 37 mm, 8 × 29 mm, or 8 × 36 mm (Biliary Wallstent, Monorail stent; Boston Scientific) were used. Post-stent dilatation was performed for 5 to 10 seconds in all cases, with 5-mm × 2-cm, 5.5-mm × 2-cm, or 6-mm × 2-cm monorail balloon catheters (Ultra-soft SV Monorail balloon catheter; Boston Scientific) inflated to 8 atm.

Completion carotid angiography was performed in all patients to assess technical results and the presence of distal spasm. Intra-arterial papaverine solution (1 mg/mL) was selectively used to treat residual carotid spasm. After removal of the sheaths the vessel access sites were closed with 5-0 or 6-0 polypropylene sutures, and the wound was closed with absorbable sutures. After the procedure all patients were observed in the recovery room for 6 hours, then transferred to a floor or telemetry bed. Clopidogrel was continued at 75 mg/day orally for at least 1 month, and aspirin was continued indefinitely. One month after the procedure, physical examination and carotid duplex scanning were repeated in all patients.

Technical failure was defined as inability to access or cross the lesion, or post-stenting residual stenosis equal to or greater than 30%. Changes in intra-procedural mental status were categorized as none, decreased, or unresponsive. TIA was defined as a focal hemispheric deficit that resolved within 24 hours. A focal deficit lasting more than 24 hours was defined as stroke. Recurrent or residual in-stent stenosis was defined as more than 50% diameter reduction as determined with duplex ultrasound scanning. Outpatient follow-up was conducted at 1, 3, 6, and 12 months after surgery.

RESULTS

All CAS procedures were completed successfully. No significant residual stenosis occurred, and the ECA remained patent in all patients. In 1 patient with a symptomatic, highly stenotic recurrent lesion diagnosed with ultrasound a few weeks earlier the ICA was found to be occluded at surgery. The occlusion was crossed, and after ascertaining wide patency of the distal, cervical ICA, it was stented with excellent anatomic resolution of the stenosis, and without complications.

Distal ICA spasm after CAS was noted in 6 patients (12%), and resolved with papaverine solution injection in 5 patients and with additional balloon dilation in 1 patient. Mean duration of the procedure was 66 minutes (range, 27-180 minutes), and mean ICA flow reversal time was 21.4 minutes (range, 9-50 minutes).

Early in the experience there was 1 postoperative ipsilateral hemispheric TIA with upper extremity hemiparesis and aphasia, which resolved within 3 hours of the procedure. Flow reversal was not effectively established in this patient, because of difficulty in placing the second introducer sheath in a small CCA. One intraoperative contralateral hemispheric TIA occurred in a patient with contralateral ICA occlusion, which resolved immediately after re-establishment of antegrade flow. One patient complained of severe eye pain without visual disturbance during the procedure, but no visual field loss was found at postoperative examination.

Among 27 patients who received local anesthetic for the procedure, CCA occlusion was not tolerated in 1 patient (3.7%) with recurrent stenosis, contralateral ICA occlusion, and contralateral stroke. This patient underwent the procedure without protection and without complications. Transient mental status changes also occurred in another patient with contralateral ICA occlusion and previous contralateral hemispheric stroke. This patient became unresponsive at the end of the procedure, but recovered immediately on re-establishment of antegrade carotid flow. The remaining 5 patients with contralateral ICA occlusion (4 patients under local anesthesia, 1 under general anesthesia) tolerated the procedure well, without complications.

In response to ICA balloon dilation we observed bradycardia or hypotension in 16 patients (32%). This vagal response was mild in 14 patients, and did not require treatment. In the other 2 patients intravenous drug administration was necessary. One of these patients sustained severe hypotension, which responded to intravenous administration of ephedrine, and the other patient sustained asystole, immediately recovering pulse and pressure after a precordial thump and atropine injection. Subsequently a pacemaker was implanted in this patient. Paradoxically, 2 patients sustained a hypertensive response to ICA balloon dilation, one of whom required intravenous treatment. Mild pain was noted during ICA balloon dilation in some patients, but severe neck pain was encountered in 2 patients, which required immediate angioplasty balloon deflation.

One patient had a seizure after inadvertent intracerebral injection of papaverine solution in excessive concentration (30 mg/mL rather than 1 mg/mL) to resolve residual ICA spasm after antegrade ICA flow was re-established. This patient was given intravenous benzodiazepine agents, and a endotracheal tube was placed, which subsequently was removed within 30 minutes without sequelae.

During the first 12 procedures there were 3 minor distal CCA dissections, which resolved after stent placement, and 1 major CCA dissection, which required repair with an interposition graft after stenting was completed. Neck wound hematoma occurred in 2 patients, but only 1 required surgical drainage, although it did not delay discharge from the hospital the day after surgery.

All patients were discharged from the hospital within 2 days of the procedure. There were no deaths or strokes at 30 days after surgery. During follow-up at 1 to 12 months (mean, 7 months) all patients remained neurologically unchanged, and carotid ultrasound scanning revealed that 49 carotid stents were patent without residual or recurrent stenosis, and 1 carotid stent was occluded at 1 month after the procedure.

DISCUSSION

Cerebral embolization is currently considered the major risk associated with CAS. It has been well documented that cerebral embolization occurs during all technical maneuvers required for CAS,[2] and that large numbers of embolic particles are detected with transcranial Doppler scanning of the middle cerebral artery during these procedures.[1,3] Because the embolic signals detected during CAS are uncommonly associated with a clinically apparent neurologic event, the significance of periprocedural embolization during CAS is not well understood. A recent prospective study of 72 patients undergoing CAS without protection revealed a 15% incidence of new ipsilateral brain infarcts detected with postoperative magnetic resonance imaging, 7% of which were clinically apparent neurologic events.[19] In another recent study of 70 unprotected CAS procedures, 29% of the patients demonstrated new ipsilateral hemispheric infarcts at magnetic resonance imaging, and 9% had new contralateral hemispheric lesions, but only 1.4% were clinically evident.[20] The latter observation suggests that embolization also commonly occurs to the untreated carotid territory, possibly secondary to arch instrumentation or crossover migration of embolic particles. Regardless of the immediate clinical significance of the embolic phenomena, these findings reveal a strong association between brain infarction and periprocedural embolization during CAS. Therefore embolization during CAS is not an inconsequential phenomenon, and every effort should be made to prevent it.

Distal protection devices reduce intraprocedural embolization during CAS, but by no means eliminate it completely.[9-11,21,22] Establishing ICA flow reversal before crossing the ICA lesion during CAS is a major advantage of the Parodi antiembolic system. In addition, the Parodi transfemoral flow reversal catheter is the only cerebral protection system that has shown rather complete elimination of intraprocedural embolization in vitro and in patients.[14,16] For that reason, we incorporated ICA flow reversal in our procedure, and enhanced ICA flow reversal by using a larger caliber, shorter arteriovenous communication from the CCA to the jugular vein. Because of the low resistance of our arteriovenous communication, our technique does not require occlusion of ECA flow to reverse flow in the ICA. Therefore our technique eliminates a technical step necessary to occlude the ECA with a balloon, required with the transfemoral system developed by Parodi.

Our initial experience is extremely encouraging because of the absence of perioperative strokes, similar to the initial clinical experience with the Parodi system,[16] and compares favorably with the results of CAS series using dista protection devices with filters and balloons.[7,12,23-25] The learning curve of our experience with this technique was associated with CCA access complications. During our first 12 cases we experienced 4 CCA dissections, 1 of which required surgical repair of the CCA. Three of these dissections occurred during the first 6 procedures, which were performed with 2 CCA introducers sheaths. After switching to a single 8F introducer sheath we experienced only 1 minor CCA dissection, which resolved after stent placement. It should be noted that we did not have any ICA dissections in our experience. Although we did not find any cases in which CCA cannulation was not posible, preoperative evaluation of the CCA with duplex scanning is advisable to identify the presence of calcification or other disease that would make the transcervical approach ill-advised. Stenotic or calcified CCAs are a contraindication for the procedure, and in patients with very low bifurcations the procedure may be difficult, and the transfemoral route is probably a safer approach. The need for a cervical cutdown of the CCA could be considered a drawback of our technique. However, we have had only had 1 wound hematoma that required surgical drainage under local anesthesia. It is necessary to consider that these 50 patients represent our initial experience with a newly devised procedure and that with increasing experience and by using specifically designed devices for the procedure a lower complication rate can be expected. Our initial experience suggests that transcervical CAS may be accomplished with a low stroke or complication rate, comparable to other approaches. Our follow-up data, however, are limited, and do not allow analysis of the long-term incidence of recurrent stenosis and freedom from stroke.

Carotid intervention through the femoral approach carries additional risks of retroperitoneal or groin bleeding or hematoma, iliofemoral arterial dissection, pseudoaneurysm formation, arteriovenous fistula, nerve injury, arterial thrombosis, extremity and visceral embolization, and ipsilateral or contralateral cerebral hemispheric embolization. The incidence of femoral access-related complications during CAS is not clearly reported in the literature. We can extrapolate from the coronary intervention experience from the last decade that a 5% to 15% femoral access complication rate may be expected, by no means an insignificant

incidence.[26] Given our low cervical access morbidity, it is possible that with increasing experience the overall morbidity with transcervical CCA may be lower than that with the transfemoral approach. An additional benefit of the transcervical approach is that it enables immediate ambulation of the patient after the procedure, facilitating performance on an ambulatory basis.

Neurologic tolerance to ICA flow reversal was excellent in 96% of our patients, a rate similar to that with protection using ICA flow reversal through a femoral catheter,[16] but perhaps better than the 85% to 95% tolerance reported during protection with distal balloon occlusion devices.[21,25] Carotid flow reversal was tolerated in all 43 patients with a patent contralateral ICA. It was not tolerated, however, in 2 of 7 patients (29%) with an occluded contralateral ICA. One of these 2 patients had immediate intolerance to CCA occlusion, and underwent stenting without protection, and the other patient was unresponsive at completion of the procedure, but recovered immediately on re-establishment of antegrade ICA flow. A similar 19% intolerance rate was found by Lawrence et al[27] in 26 patients with contralateral ICA occlusion undergoing carotid endarterectomy under local anesthesia.

Ipsilateral brain perfusion during ICA flow reversal depends on hemispheric resistance to collateral flow from the posterior circulation, the contralateral hemisphere, and pial vessels, and preservation of ipsilateral hemispheric oxygen saturation with this mechanism has been documented during ICA flow reversal in a subset of these patients.[18] Inasmuch as cerebral perfusion pressure and mean systemic arterial pressure are linearly related, increasing mean systemic arterial pressure with pharmacologic agents would possibly further decrease the rate of neurologic intolerance to ICA flow reversal.[28,29] With increasing experience with transcervical CAS the duration of the procedure and of carotid flow reversal should be significantly shortened, and improved neurologic tolerance can be expected. Nevertheless, our initial experience suggests that patients with contralateral ICA occlusion are more likely to not tolerate flow reversal, and a different method of cerebral protection should be considered in these patients. The use of transcranial Doppler monitoring of the middle cerebral artery flow characteristics during the procedure may help to predict which patients are more likely to tolerate cerebral flow reversal.

The vagal response to ICA balloon inflation during CAS is unrelated to the use of protection devices. In our experience, 16 patients (32%) sustained a vagal response, but only 2 of these patients (12%) required treatment. The report by Leisch et al[30] corroborates our experience, finding that 40% of patients undergoing CAS reacted to carotid body stimulation during balloon inflation, most commonly with short-term hypotension, but without clinical symptoms and not associated with periprocedural cerebral complications. Of interest, hypertension developed in 2 patients in our series in response to ICA balloon inflation, and 1 of these patients required intravenous drug administration.

Distal protection with filtering devices has the advantage of not interrupting antegrade carotid flow during CAS. However, this benefit may be offset by a 2% to 6% rate of filter placement failure,[26,27] risk for lesion crossing before filter protection is in place, and intrinsic risks and limitations of filters in capturing embolic debris.[8] Transfemoral access for CAS may not be feasible in patients with severe occlusive disease of the aorta and iliofemoral arteries. CCA cannulation may be impossible in patients with tortuous supra-aortic trunks or unfavorable arch anatomy, and aortic instrumentation may be ill-advised in patients with emboligenic aortic plaque. In addition, distal protection device deployment failure occasionally occurs. It is difficult to quantitate the individual incidence of these conditions, because they typically lead to aborted procedures that mostly are unreported. The combined incidence of all of these problems could amount to a significant rate of transfemoral cerebral protection failure on an intention-to-use basis. When CAS is indicated in patients with unfavorable anatomy or emboligenic plaque, the transcervical approach may be a technically easier and safer option.

Finally, the inclusion of cerebral protection devices significantly increases the cost of CAS, an already technologically expensive intervention, whereas the transcervical approach with ICA flow reversal has the advantage of providing cerebral protection without the additional cost of protection devices.

In summary, our initial experience suggests that transcervical CAS with ICA flow reversal for cerebral protection can be performed safely with a low neurologic complication rate. The procedure is well tolerated with local anesthesia in most patients. The procedure is feasible in most situations where the transfemoral route is impossible or contraindicated. It overcomes the limitations of distal protection systems, and eliminates their cost. Thus transcervical CAS with ICA flow reversal is a safe and effective alternative in patients in whom carotid stenting is indicated.

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DISCUSSION

Dr Robert W. Hobson (Newark, NJ). I have questions in 3 or 4 areas. We have restricted performance of these procedures to transfemoral methods. Only 2% of our 194 consecutive procedures were done by direct cervical carotid exposure and cannulation when femoral arterial access was compromised. We have not observed your predicted 5% to 15% local complication rate with femoral cannulations.

My first question is this: What has your complication rate been with other transfemoral endovascular procedures? Do you have a group of carotid artery stent procedures using conventional transfemoral cannulations for comparison so that we get some appreciation of the differences?

Secondly, nearly half of your procedures were performed under general anesthesia with the indicated incision. How do you select patients for the transcarotid procedure as opposed to simply going ahead with a carotid endarterectomy? Should this procedure be reserved for high-risk patients, who really constituted 80% of your sample?

Thirdly, can you provide us a little additional detail about the flow reversal technique? You injected contrast to confirm reversal and, in the manuscript, described a rationale for avoiding balloon occlusion of the external carotid. If blood were aspirated through the common carotid arterial sheath during and after carotid artery stenting, would you also predict flow reversal? And if so, could you avoid the use of the internal jugular fistula altogether, thereby making it, perhaps, a little bit easier to perform.

You reported an 8% incidence of common carotid artery dissection. Now, presumably the dissection occurs at the point your sheath goes into the artery, so you can't cover that with the stent. So could you describe a little bit more about those dissections and how you might prevent them?

Finally, you had a 32% incidence of hypotension and bradycardia. Give us a little sense of your clinical protocol. Do the patients get antihypertensives on the morning of the procedure? Do you use atropine routinely?

You had one asystole, which must have been a difficult time for you in the operating room. And do you always, therefore, have a transvenous pacemaker available?

I urge you to continue to collect clinical data on transcervical carotid artery stenting. In my opinion, it will not replace transfemoral carotid artery stenting, but it is a method that all vascular surgeons should acquire for cases with compromised femoral access.

Dr Enrique Criado. I cannot tell you our current femoral access complication rate, but it is my impression that is rather low. The complication rate I quoted is from the cardiology literature for coronary interventional procedures. It is perhaps early to know what is going to be the femoral complication rate specifically for carotid intervention.

I agree with you, this procedure should still be reserved for high-risk patients, no question about it. I would admit, however, that a number of our patients were not necessarily high-risk patients.

In regard to the reversal of flow in the carotid artery, I believe that the main advantage of our technique is that it provides a high-flow fistula that washes out all debris throughout the procedure from the very beginning. I think we need to do much more work, as you suggested, including intraoperative studies with transcranial Doppler to see what happens in the middle cerebral artery with the flow reversal and what is the incidence of HITS during the procedure. Dr Parodi, however, has documented that the number of HITS during this procedure, at least those done transfemorally with another balloon in the external carotid artery, is rather small if not inexistent.

In terms of the bradycardiac events in response to balloon inflation in the internal carotid artery, we do not have a specific protocol owing to the tendency of the responses to be rather mild. We see a number of bradycardias and mild hypotensions, but most of them have been asymptomatic and have not required treatment.

We had 1 episode of asystole that responded immediately to atropine and to a precordial thump. We do not have temporary pacemakers available, but I think they should perhaps be in the operating room; however, we certainly have drugs available to be injected intravenously.

Dr Maciej L. Dryjski (Buffalo, NY). Could you explain why you chose this approach versus the femoral approach? Do these patients have a problem with the femoral arteries, or was this just because you found it easier? And the second question is that an 8% incidence of carotid dissection seems to be extremely high, so do you still plan to do these procedures?

Dr Criado. Well, first of all I stated that the rationale for the transcervical approach is to avoid the limitations of other protection devices, to provide what we believe a better, perhaps superior way of inverting flow in the internal carotid artery to provide the best protection during the manipulation of the lesion in internal carotid artery. There was nothing wrong, that I can recall, with the femoral pulses in most of these patients.

In regard to the dissections, we had 4 during the first 12 cases. And at the beginning of our experience, we were using 2 introducers in the CCA, 1 to occlude the external and the other to actually conduct the procedure. We very soon found out that that was not a good idea, and we switched to a single introducer sheath, which made the procedure easier.

All dissections, actually, were not at the entry site, but were more distal, probably made by the introducer sheath's tip. Carotid access is probably the riskier, more difficult part of the procedure. Once we switched to the 4F micropuncture kit and a single CCA sheath, we have not had any problems. However, the potential problems are there. I would like to remind you that we also see a good number of dissections in the femoral and iliac arteries from interventional access.

I think, considering that this is a very preliminary experience, the results are quite encouraging. And unless somebody else proves to me that protection can be provided better by other means, we should continue to do it.

Dr John Blebea (Philadelphia, Pa). Your approach certainly has some advantages, not the least of which is that it still maintains the procedure within the purview of vascular surgeons. Have you measured the actual flow within the loop? Because I can see on the angiogram how you have reversal of flow, but, once you use the same introducer sheath for your stent and the balloon, there is no question that the backflow through that sheath is going to be decreased. So during the actual procedure, do you, in fact, have continued reversal of flow, and is that flow going to be sufficient and is the lumen large enough so if you get larger particulate matter? In fact, does it have room to reverse and go through your arteriovenous fistula instead of just staying outside the sheath and as soon as you pull out it's still embolized distally?

Dr Criado. First of all, we obviously don't have a way of measuring intraprocedural flow. But if you look at the caliber of the size of the sheaths we use, which are 8Fs, and if you put one of these Monorail balloons inside, or even the Monorail stent, you will see that the Monorail balloon or stent occupies actually a very small part of the cross-sectional area of the sheath. So there's actually plenty of room for reverse flow around our devices.

This was one of the limitations, or is one of the limitations of the PAES, of the Parodi Antiembolic System—it is not only smaller in size (a 7F sheath) but it is so long that the resistance is higher.

I agree with you, but throughout the procedure when injections of dye are often done by hand, with very small injections to ascertain position and whatnot, every single time you see the flow upon reestablishment of the fistula, the flow is automatically reversed. Flow reversal, however, is proportional to the gradient from your back stem pressure, as you can imagine, and your internal jugular vein pressure. But in general, sometimes it's faster, sometimes slower, depending on that back stem pressure. But it is always there. We have not seen a single case with back stem pressure, where the flow was not reversed. Occasionally, however, I admit, it is very stagnant when the carotid lesion is very tight. And after you actually open up the lesion with the stent or the balloon, then you see that the flow reversal is actually much faster.

Dr John J. Ricotta (Stony Brook, NY). I think you should comment a little bit on the contralateral occlusion patients and the patients who may or may not tolerate flow reversal.

Dr Criado. In the whole series, there were actually 7 patients with contralateral ICA occlusions, 6 of which were done under local. Of those 6 under local, where we could actually monitor the neurologic status throughout the procedure, 4 tolerated the procedure without any problems, which was better than I expected. This is actually in line with what happens with carotid occlusion during carotid endarterectomy, if you review the literature. Actually, there is a nice article by Lawrence documenting that grade of tolerance to carotid occlusion.

One patient did not tolerate common carotid occlusion at all, from the very beginning. We would cinch down the CCA and the patient would just try to get off the table. It was very dramatic. So that patient had recurrent stenosis. We conducted the procedure without protection, because I believe that recurrent stenosis for endarterectomy perhaps has a lower embolic rate.

And the other patient did well throughout the procedure. And when we were pretty much done, and were just about to dilate the stent following the completion, he became unresponsive. And a few seconds later, we opened up, we reestablished antegrade flow towards the brain, and he recovered right away.

The same thing happened with a contralateral TIA, in a patient with a previous stroke. It was a motor TIA and the patient had had similar symptoms when he had the stroke months before. Upon re-establishment of antegrade flow, the motor deficit actually recovered and disappeared.

So that has been my experience. However, having said that, I think you have to very careful and very cautious when you do this procedure in patients with contralateral occlusion. Dr Parodi suggests, and we may try this, that if you increase the mean systemic arterial pressure with phenylephrine, or other drugs perhaps, the threshold for tolerance to flow reverse in patients with contralateral occlusion may go higher and some of these patients who might not be able to tolerate the procedure under normal circumstances may do so with a little higher pressure. I'm not sure I'm willing to try that because of the pharmacologic intervention. Perhaps, those patients are better served by other means. I'm not sure.

Dr Michael A. Golden (Philadelphia, Pa). I did have a question about the distance between the tip of your sheath in the carotid and the Rumel tourniquet. It seems to me that you have sort of a cul-de-sac dead space there that would potentially allow debris to not be evacuated by the tip of the sheath, since I assume the tip of the sheath has to be in the artery enough that the sheath doesn't end up coming out while you're moving things back and forth.

Dr Criado. We apply a catheter with a beveled tip around the actual introducer sheath to limit introduction of the sheath to 3 cm into the carotid. We don't want to have the sheath all the way up because it could create an additional injury. That could actually be further shortened. You have to bear in mind, these are commercially available devices that are used for other purposes. We're now working to design a catheter that is a little more specific for the neck and create a gadget that would make the procedure safer and easier.

But you're right, you're potentially creating throughout the procedure a small area of stagnant flow where the debris could accumulate. But, as long as the flow is reversed throughout the procedure by the venturi effect, the debris is preferentially going to follow the path of least resistance with the flow, which would be into the sheath and into the internal jugular.

Dr Sal Cuadra (Newark, NJ). You mentioned the high proportion of patients needing general anesthesia. I'm not sure if you gave detail. Were these patients who had to be converted to general anesthesia because there was a problem intraoperatively, or were these just started as general anesthesia from the beginning of the case by surgeon preference?

Dr Criado. It happens in all initial experiences. We try to be as cautious and careful at the beginning. And our decision, when we started doing these procedures, which were started overseas with my colleagues, is we just had to do it under general first. After more experience and developing the technique a little better, we felt comfortable in initiating the cases under local. Now, it's the opposite. Now, it's only occasionally that the patients either request or, perhaps, need to be converted to general. So I don't think there's any reason to do this under general.

Dr Linda Harris (Buffalo, New York). Have you considered evaluating these patients with transcranial Doppler (TCD) scans to see whether or not there are any distal emboli? And also, are you concerned at all about pulmonary emboli or paradoxical emboli with your technique?

Dr Criado. Absolutely. My chairman is very supportive, and I'm hopeful that he will buy us a TCD soon so we can actually document this. We already have a TCD scheduled for a case on Monday. But Dr Parodi has looked at a TCD of these patients through the femoral approach and the low incidence of HITs is remarkable.

In regard to the paradoxical embolization, that's an excellent point. Some of these patients may have a right-to-left communication and there's always a potential for peripheral or cerebral embolization. That is fixable with a filter. The reason we did not use a filter initially was that the only filter we had available was the commonly available blood filter, which may actually increase the resistance of the fistula to a point where the flow is not efficient enough. But we're willing to use a filter when we find one which does not limit flow reversal, although I think that the potential for paradoxical embolization is rather low.

Dr Michel Makaroun (Pittsburgh, Pa). With so few long-term follow-up results of how the stent is going to behave in the carotid artery, how would you convince a surgical audience and their patients that the incision you are making is any different or any less stressful than a carotid endarterectomy, especially since the surgeons are having a hard time buying that the puncture of the femoral artery might be a little bit less stressful or involved than an incision in the neck and the president of the Society does about a 2.0 to 2.5-cm incision for essentially all of the carotid endarterectomies. So how do we justify this going into the neck and making the incision just to put a stent, when you can do with about the same incision the carotid endarterectomy?

Dr Criado. Well, I'm not trying to justify anything. I think that it's rather obvious, and I think this is a very, very small, very quick common carotid dissection. By no means is it equal to a full-fledged carotid endarterectomy.

You could argue that carotid endarterectomy is associated with peripheral nerve injury. We still have a few of those. But obviously, you do not have that complication with this approach.

I do not agree that this kind of cutdown is equivalent to a carotid endarterectomy. The main thrust of this is to actually try to investigate a procedure which may produce the fewest number of emboli during carotid artery stenting. That's the main goal of this procedure. I'm not trying to justify the nonuse of the femoral or any other approaches. But I think we need more data and perhaps, eventually, some comparative studies to see what comes out on top.