Duplex–assisted internal carotid artery balloon angioplasty and stent placement: A novel approach to minimize or eliminate the use of contrast material

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Background: **Carotid artery balloon angioplasty and stenting (CBAS) is emerging as an acceptable alternative to carotid endarterectomy in selected high-risk patients. Conversely, patients with pre-existing renal impairment, diabetes, or both may be harmed by the nephrotoxic contrast agents required during CBAS. We attempted to limit or eliminate the use of contrast material during CBAS.**

Methods: **Eighteen patients with severe carotid stenoses (>70%) underwent CBAS at our institution over the last 12 months with duplex scan–assisted CBAS. Of these, 12 were primary procedures, and 6 were performed for carotid re-stenosis. Fourteen patients (78%) were neurologically asymptomatic. The average age of these patients was 75 ± 11 years (range, 44-92 years). Hypertension, chronic renal insufficiency (serum creatinine level ≥1.5 mg/dL), coronary artery disease, diabetes, and smoking were present in 89%, 67%, 59%, 33%, and 28% of patients, respectively. Preoperative duplex carotid mapping was performed in all cases. All procedures were performed with patients under local anesthesia and light sedation.**

Results: **An ATL HDI 5000 scanner with the SonoCT feature was used. The common femoral artery was cannulated with a single-entry needle under direct ultrasound visualization. Fluoroscopy was used to assist passage of the guidewire into the aorta and the common carotid artery. In only four cases (22%) was an aortic arch angiogram obtained. Selective catheterization of the internal and external carotid arteries was performed under ultrasound guidance. The distal cerebral protection device (17 cases) was placed under fluoroscopic guidance. Balloon width and length were chosen according to ultrasound measurements. Balloon and stent deployment were successfully achieved with ultrasound guidance alone in all cases. Appropriate stent apposition and resolution of the stenosis was confirmed by duplex scanning in all cases. Five patients (28%) were noted to have low (<100 mL/min) internal carotid artery volume flow after stent deployment (range, 20-88 mL/min; mean ± SD, 50 ± 25 mL/min). The internal carotid artery volume flow increased immediately after Filterwire retrieval in all cases and ranged from 136 to 400 mL/min (mean, 245 ± 107 mL/min). This increase was statistically significant (*P* < .02). No ipsilateral strokes or deaths occurred during follow-up from 1 to 12 months (mean follow-up, 5 months).**

Conclusions: **Duplex scan–assisted CBAS is feasible and may reduce the need for intra-arterial contrast injection in selected patients deemed at high risk for renal failure from nephrotoxic contrast material. Additional advantages include direct visualization of the puncture site, precise position of the balloon and stent, and B-mode and hemodynamic confirmation of the adequacy of the technique. (J Vasc Surg 2005;41:409-15.)**

Modern duplex scanners provide excellent images and reliable hemodynamic parameters of the carotid arteries and have increasingly been used as the sole preoperative method to evaluate the exact location, degree, and extent of a carotid lesion in the neck. These scanners provide up to 10-fold magnification coupled with the superb resolution of the arterial wall allowed by the fairly superficial location of the carotid arteries in the neck. Accordingly, it is reasonable to assume that duplex methods can also be used to guide wires, sheaths, balloons, and stents during performance of carotid balloon angioplasties and stenting (CBAS). Theoretically, the visualization of the entire arterial wall by duplex scan as opposed to arteriography may provide superior information regarding a number of steps during CBAS, including (1) positioning of the balloon and stent regardless of motion artifacts, (2) apposition of the stent to the arterial wall, and (3) B-mode and spectral analysis confirmation of the adequacy of the procedure. Conversely, duplex scanning of the aortic arch is limited by the chest wall anatomy, and fluoroscopic guidance is required for cannulation of the aortic arch vessels. Additionally, placement of cerebral protection devices in the distal internal carotid artery (ICA) calls for the use of fluoroscopy, because duplex insonation of this segment is difficult. The purpose of this article is to report on our early experience with 18 duplex scan–assisted CBAS. To our knowledge, this is the first such report in the literature.

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Competition of interest: none.

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METHODS

Patients. Eighteen patients who presented with severe (>70%) carotid stenoses underwent ICA angioplasties at

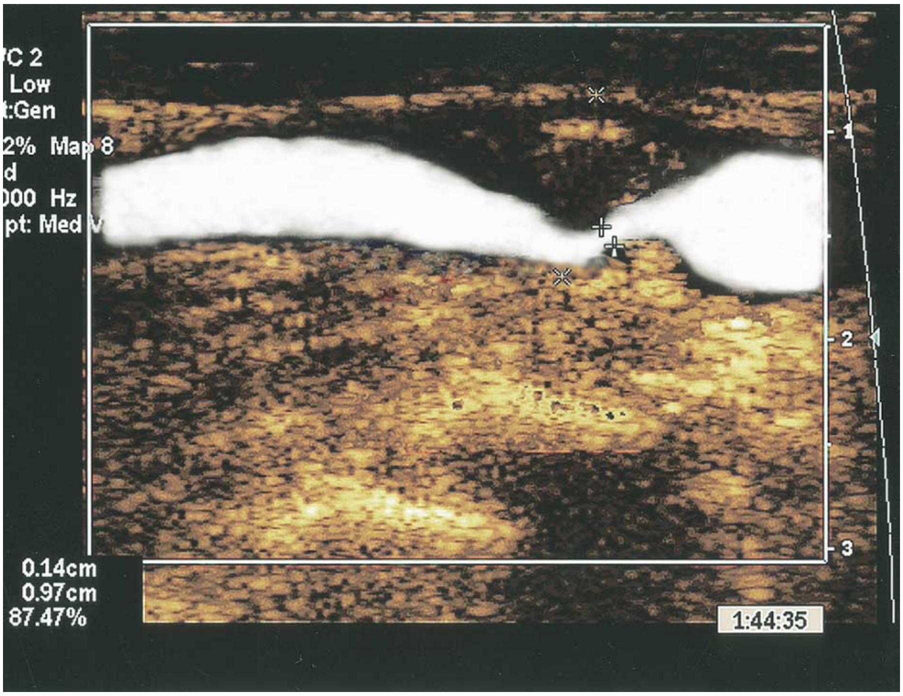

Fig 1. Power Doppler image of the common and internal carotid arteries, outlining a severe stenosis at the proximal internal carotid artery.

our institution (Fig 1). Twelve (67%) of these lesions were primary, and the remaining six (33%) were recurrent stenoses after carotid endarterectomy (CEA). The interval between the CEA and re-stenosis varied from 7 to 192 months (mean ± SD, 59 ± 70 months). Fourteen stenoses (78%) were asymptomatic. Patients' ages ranged from 44 to 92 years (average, 75 ± 11 years). There were 14 men (78%) and 4 women (22%) in this series. Concomitant risk factors such as hypertension, coronary artery disease, diabetes, and tobacco use were present in 89%, 56%, 33%, and 28% of patients, respectively. Additionally, 12 patients (67%) had increased serum creatinine levels (≥1.5 mg/dL). Serum creatinine in these patients ranged from 1.5 to 4.2 mg/dL (mean, 2.2 ± 1 mg/dL). The remaining six patients had no major contraindications to contrast material, but they were informed about the two different approaches and opted for duplex–assisted CBAS. Since the first duplex–assisted CBAS performed in October 2003 (a total of 18 cases), only 7 CBAS cases have been performed in the standard fashion. It is important to note that of the last 14 consecutive CBAS cases, all were duplex-assisted. Patients were selected according to patient and surgeon preference; this was not influenced by the indication for the procedure, anatomic considerations, or cardiovascular risk factors. Special informed consents were obtained in all patients. All patients were treated with aspirin the night before the procedure, and they all were receiving clopidogrel on discharge.

Preoperative evaluation. Preoperative duplex carotid mapping was performed in all patients and included (1) measurements of the ICA stenosis degree in sagittal and transverse planes; (2) lumen diameter measurements of the distal common carotid artery (CCA) and distal ICA; (3) plaque extension length; and (4) presence of severe tortuosity of the ICA

Technique. An ATL HDI 5000 scanner (Phillips Medical Systems, Bothell, Wash) with the SonoCT feature was used in all cases. A linear 7-4 MHz probe was required for insonation of the common femoral artery (CFA), the CCA, and its branches. A digital mobile fluoroscopic imaging system (OEC 9800 or OES 9800-MD; GE Medical Systems, Fairfield, Conn) with road-map capabilities in the operating room was used in all cases. The duplex scanner was positioned by the head of the operating table ipsilateral to the carotid lesion. The duplex monitor was directed toward the interventionist. The mobile C-arm was placed on the opposite side of the carotid lesion to allow free motion despite the presence of the duplex scanner.

All cases were performed with patients under local anesthesia. The least diseased CFA with the best spectral analysis waveform, as demonstrated by duplex scanning, was chosen for the access site. The CFA was cannulated in a retrograde fashion with a single-entry needle under direct duplex visualization. The needle was then exchanged over a metal wire for a short 5F sheath. Fluoroscopy was used to assist manipulation of the 0.035 inch Glidewire (Boston Scientific Corp, Natick, Mass) into the aortic arch. Guiding catheters used in this series for selective catheterization of the CCA included the Bern selective angiographic catheter (Boston Scientific) and the Vitek cerebral catheter (Cook

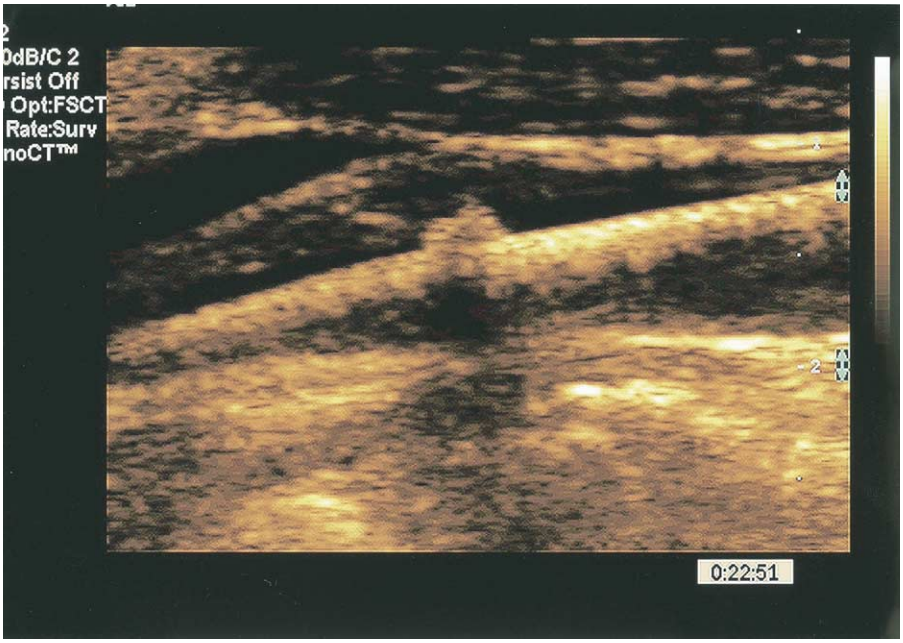

Fig 2. Stent positioned across the lesion in the internal carotid artery.

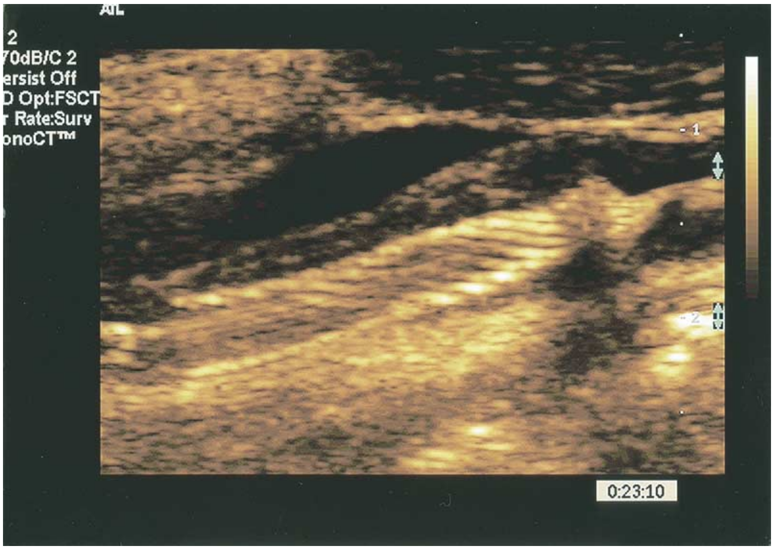

Fig 3. Deployment of the distal stent portion in the internal carotid artery.

Inc, Bloomington, Ind). Duplex scanning was used to confirm the presence of the guidewire in the CCA. Duplex scanning was also used to guide the wire into the external carotid artery with the help of the guiding catheter. Next, this wire was exchanged for an Amplatz stiff wire to allow for safe placement of a 6F Shuttle SL introducer sheath (Cook Inc), which was parked in the CCA approximately 2 to 3 cm proximal to the bifurcation. All maneuvers in the neck were performed under duplex guidance. The Filter-wire EX embolic protection system (Boston Scientific) was negotiated into the ICA and beyond the stenosis under ultrasound guidance. From this point, fluoroscopy was used to position the filter 4 to 6 cm distal to the area of stenosis in the ICA. Next, a prestent balloon dilation of the ICA lesion was performed under ultrasound guidance. This was followed by placement of a biliary monorail Wallstent (Boston Scientific) across the lesion and deployed under ultrasound monitoring (Figs 2-4). Stent diameter and length were chosen according to the proximal and distal arterial diameters and the lesion length as measured by

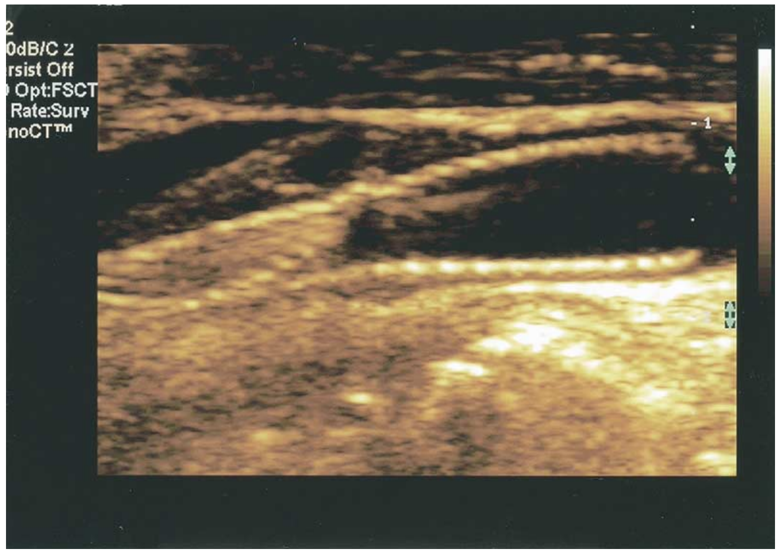

Fig 4. Proximal portion of the stent deployed in the common carotid artery.

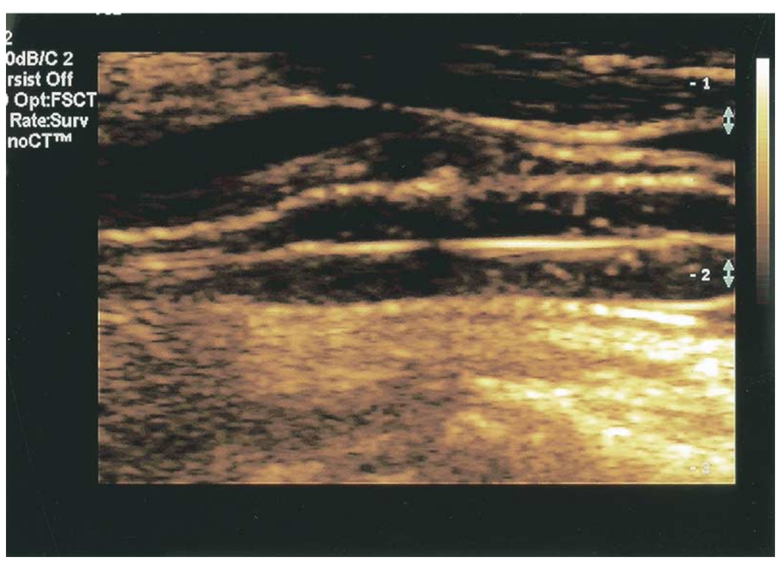

Fig 5. Balloon dilation of the carotid artery stenosis after stent placement.

preoperative duplex mapping. After stent deployment, a larger balloon was used to eliminate any residual stenosis (Fig 5). A completion duplex scan was performed to confirm (1) good stent apposition against the arterial wall, (2) wide patency of the native and stented CCA and ICA segments, and (3) absence of thrombi, flaps, or other abnormalities (Fig 6). In addition, hemodynamic parameters including peak systolic velocity, end-diastolic velocity, resistive index, and mean volume flow were obtained from the distal (poststent) ICA in all cases before and after Filterwire removal (Fig 7). Completion ICA arteriograms with a small amount of dye were performed for correlation with duplex scan results according to the surgeon's preference. Finally, the Shuttle introducer sheath was exchanged for a 6F short sheath over a stiff wire.

RESULTS

Intraoperative findings. Technical success, as confirmed by completion duplex image and hemodynamic parameters, was achieved in all cases. Completion contrast arteriography was obtained in the first four cases (22%) with small amounts of dye (Magnevist®, Berlex Laboratories, Wayne, NJ, three cases; Visipaque™, Amersham Health, Princeton, NJ, one case) to validate the duplex findings. Stent apposition was achieved all cases. Postprocedural

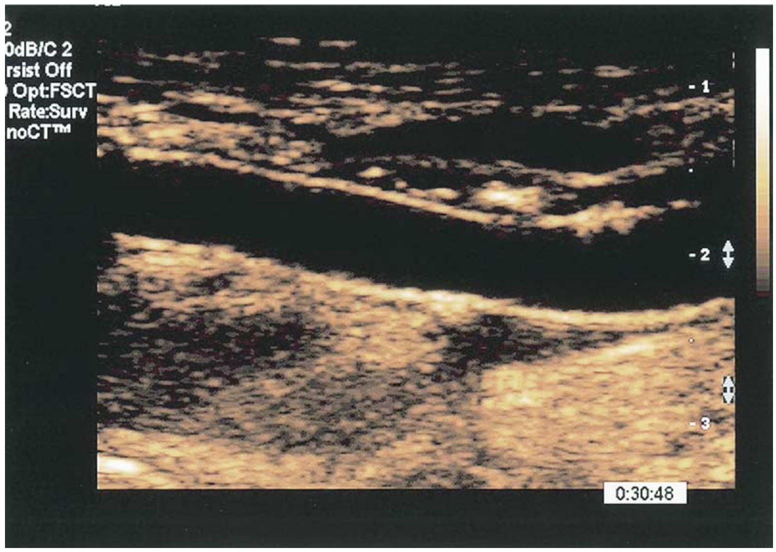

Fig 6. Completion B-mode image shows unobstructed common and internal carotid arteries.

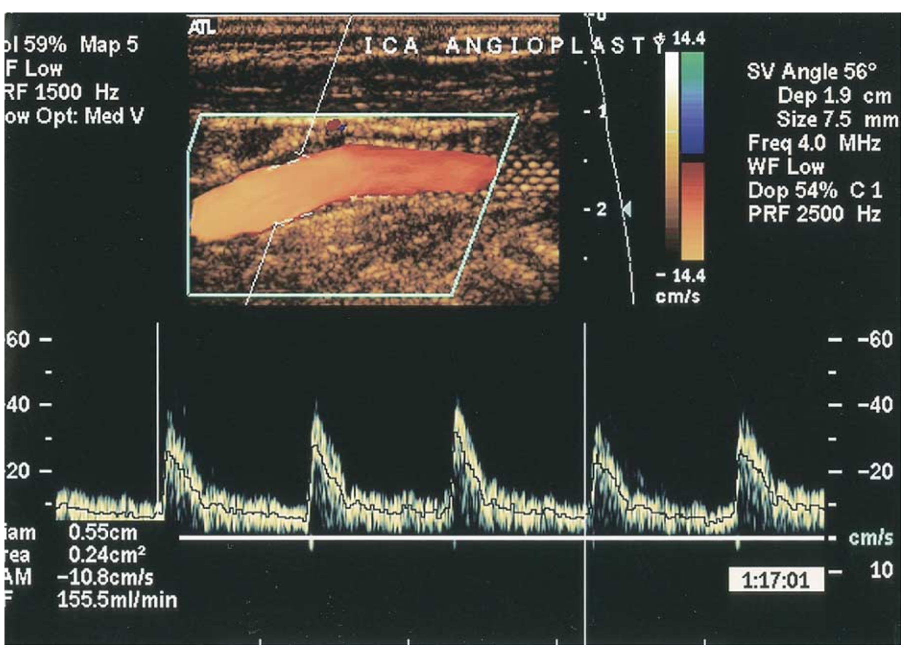

Fig 7. Peak systolic velocities decreased from 487 to 40 cm/s after carotid balloon angioplasty and stenting. As shown, the internal carotid artery volume flow is 155.5 mL/min.

biplanar cerebral arteriograms performed in 10 patients (56%) did not reveal any defects.

Significant bradycardia (<50 bpm) during balloon inflation was observed in seven cases (39%). None of these required atropine injections because patients' cardiac rhythms normalized after they coughed.

Atherosclerotic debris was captured by the filter in 6 (35%) of 17 cases. Of these, five (42%) were primary procedures, and one (20%) was a re-stenosis.

Intraoperative ICA hemodynamic parameters. Hemodynamic parameters obtained from the ICA immediately before and after Filterwire removal are depicted in Table I. It is of interest to note that in all 17 cases, there was a documented increase in ICA volume flow (ICAVF). The percentage increase in these cases varied from 20% to 1245% (mean, 217% ± 343%). Five patients (28%) were noted to have low (<100 mL/min) ICAVF after stent deployment (range, 20-88 mL/min; mean, 50 ± 25 mL/

Table I. Comparison of hemodynamic parameters obtained in the stented ICA before and after withdrawal of the cerebral protection device (Filterwire EX) in 17 patients

ICA parameter	*Filterwire in*		*Filterwire out*		*P value*
	Mean ± SD	*Range*	*Mean ± SD*	*Range*	
PSV (cm/s)	54 ± 25	7-98	81 ± 20	44-123	<.002
EDV (cm/s)	16 ± 8	0-32	26 ± 7	14-38	<.001
RI	0.7 ± 0.12	0.54-1	0.67 ± 0.1	0.58-0.83	.43
VF (mL/min)	123 ± 64	20-260	247 ± 93	135-448	<.0001

ICA, Internal carotid artery; *PSV,* peak systolic velocity; *EDV,* end-diastolic velocity; *RI,* resistive index; *VF,* volume flow.

min).[1] ICAVF increased immediately after Filterwire retrieval in all cases and ranged from 136 to 400 mL/min (mean, 245 ± 107 mL/min). This increase was statistically significant ($P < .02$).

Postprocedure mortality and morbidity. There were no early (30-day) postprocedure deaths in this series. None of the patients had an ipsilateral stroke. One patient had a small contralateral cerebellar infarct with complete clinical recovery within 3 weeks. Wire and catheter manipulation in the aorta and its branches did not cause clinically detectable lower extremity or visceral embolization in this series. Pseudoaneurysms, arteriovenous fistulas, or hematomas did not occur as a result of the femoral puncture.

Procedure duration. The duration of the procedure in all 18 cases varied from 34 to 161 minutes, with a mean of 72 ± 30 minutes. This was calculated from the time of cannulation of the CFA to removal of the guiding sheath. The duration of the procedure in 16 of these cases varied from 34 to 91 minutes, with a mean of 64 ± 19 minutes. The remaining two cases were outliers: (1) the first case of the series (161 minutes) and (2) one of the two patients who had a bovine arch in whom the left CCA was cannulated without an arch arteriogram. The average time (39 ± 25 minutes) required for cannulation of the left CCA (12 cases) was significantly longer ($P < .04$) than the average time (20 ± 9 minutes) spent to cannulate the right CCA (6 cases).

Follow-up. All patients are alive with widely patent ipsilateral carotid arteries by duplex studies 1 to 12 months (4.9 ± 3.9 months) after CBAS.

DISCUSSION

Duplex arterial mapping as a sole preoperative diagnostic modality is an acceptable alternative to standard contrast arteriographic studies before carotid surgery.[2] The former modality is particularly advantageous for patients at increased risk of developing contrast-induced renal failure. These are patients with diabetes mellitus, pre-existing chronic renal failure (serum creatinine ≥1.5 mg/dL), or both. Acute renal insufficiency may develop in 8% to 31% of diabetic patients who receive intravenous injection of contrast material.[3-6] Although most of these patients will return to precontrast renal function levels, they may be subjected to delayed hospital discharge, a series of blood tests, and noninvasive studies, as well as specialty medical consultations. Similarly, up to 42% of patients with pre-existing chronic renal failure may experience deterioration of their renal function, and up to 20% of these patients may require hemodialysis treatments.[6] Furthermore, up to 38% of diabetic patients with azotemia may develop contrast-induced renal failure.[4] Over the last 6 years it has been our policy to obtain magnetic resonance angiograms only in cases in which duplex scanning was not completed because of severe calcification of the arterial wall or when a more proximal or distal lesion was suspected by duplex scan. Invasive contrast arteriography was not deemed necessary in more than 1200 consecutive CEAs during this period of time in our service.

Unquestionably, the higher-resolution capabilities of the newer scanners allow for excellent and reliable images of the arterial tree. Thus, it is expected that interventionists would take advantage of this noninvasive modality to guide some of their procedures. Indeed, vascular ultrasound scan–guided therapeutic procedures now include thrombin injection for pseudoaneurysms of the femoral arteries, placement of inferior vena cava filters, and obliteration of a large and incompetent saphenous vein with radiofrequency.[7-10] Recently, some authors have recognized the potential of this technique in guiding endovascular therapy for occlusive arterial disease in the lower extremities. They have published on a series of ultrasound–guided balloon angioplasties for short superficial femoral artery stenoses in selected cases, with acceptable early results.[11]

Herein, we have introduced a new application for duplex–guided therapy to relieve severe stenoses of the extracranial carotid arteries. This preliminary experience suggests that the proposed approach is feasible, effective, and safe. However, we want to emphasize that our experience is embryonic and that increased experience is mandatory before a more liberal approach is proposed with this technique. Still, we were quite impressed with the fact that we had optimal visualization of the CCA, as well as the internal and external carotid arteries, in all cases. This greatly facilitated selection of the proper size of balloon and stent because precise measurements of the vessel diameter and the extent of the lesion were easily obtained by duplex scanning. Moreover, apposition of the stent to the vessel wall was routinely confirmed by ultrasound imaging, and, whenever necessary, we re-ballooned the unopposed portion of the stent. One other advantage of using duplex scanning instead of arteriography relates to motion artifacts, which are quite common during the performance of a carotid angioplasty and often require repeated injections of contrast material to ensure proper placement of the balloon catheter and the stent. Duplex– guided positioning of these catheters is unaffected by motion because there is continuous insonation of the target vessel.

One cannot underestimate the importance of the presence of a well-trained, experienced, registered vascular technologist during this procedure. The technologist must be knowledgeable of the arterial anatomy in the neck and must possess extensive experience in duplex scanning of the carotid arteries. The duplex monitor should be placed at a comfortable distance from the interventionist, who has to accompany every step of the procedure, while the technologist optimizes the image. Unless there is excellent visualization of the diseased arterial segment and the carotid bifurcation, one should resist the temptation to proceed with duplex scan guidance and convert to arteriography. In cases of severe arterial calcification at the carotid bifurcation, one should be discouraged from proceeding with duplex–assisted CBAS.

We have previously shown the importance of ICAVF measurements during CEA as predictors of postoperative stroke. In addition, we have observed that ICAVFs less than 100 mL/min were associated with either severe spasm or intracranial carotid artery disease.[1] In this series, 5 of 18 cases had low ICAVF (mean, 50 ± 25 mL/min; range, 20-88 mL/min) documented after CBAS but before removal of the Filterwire. Significant improvements in ICAVF (mean, 245 ± 107 mL/min; range, 136-401 mL/min) were noted immediately upon withdrawal of the Filterwire and either harbored large amounts of debris or were coated with a fibrin film. One of these patients had a watershed contralateral stroke with no clinical neurologic sequela and a normal postprocedural cerebral arteriogram.

The question of whether multiplanar cerebral arteriography should routinely be performed in cases of uneventful CBAS remains to be answered. Certainly, there are potential complications associated with this examination, including embolization, arterial spasm, and allergic reactions. In our opinion, completion duplex scanning is mandatory to assess the adequacy of the technique and to document the expected hemodynamic improvement. Conversely, if neurologic deficit occurs during or immediately after CBAS, we will obtain a cerebral angiogram and treat the patient accordingly. Another question that has surfaced during our study and our intent to minimize the amount of contrast material is whether an arch arteriogram is mandatory. Because our experience is so small, we are reluctant to present a firm opinion regarding this question. Suffice it to say, we now routinely recommend obtaining a magnetic resonance angiogram of the aortic arch, primarily to identify a possible bovine aortic arch that would complicate blind cannulation of the left CCA.

In summary, our preliminary data with duplex scan–assisted CBAS show that this approach is feasible and effective in achieving excellent anatomic and hemodynamic improvements, with no complications directly related to the imaging technique. Caution should be exercised with duplex–assisted CBAS until a much larger experience is collected. Meanwhile, patients who are severely allergic to contrast material or have significant renal insufficiency may benefit from our proposed approach.

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