Duplex-guided balloon angioplasty and stenting for femoropopliteal arterial occlusive disease: An alternative in patients with renal insufficiency

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Background: The technique of balloon angioplasty of infrainguinal arteries requires standard arteriography and fluoroscopic guidance. We attempted to perform this procedure under duplex guidance to avoid the use of nephrotoxic contrast material and radiation exposure in patients with renal insufficiency.

Methods: Over 16 months, 28 patients (17 men) with serum creatinine levels of 1.5 mg/dL or more underwent 37 lower extremity duplex-guided balloon angioplasties at our institution. Ages ranged from 58 to 92 years (mean ± SD, 74 ± 9 years). Disabling claudication was the indication in 24 cases (65%), and critical ischemia, in 13 cases. Preoperative duplex arterial mapping showed severe superficial femoral artery and/or popliteal artery stenoses in all cases. No arterial occlusions were treated in this series. Seven procedures (19%) were performed for restenosis. The ipsilateral common femoral artery was cannulated in 32 cases (86%), and the contralateral common femoral artery, in 5 cases (14%), under direct duplex visualization. Contralateral common iliac artery cannulations were performed with the help of fluoroscopy. By using sonographic visualization, a guidewire was directed into the origin of the superficial femoral artery, across the diseased segment, and into the popliteal artery. The diseased segment was then balloon-dilated. Balloon diameter and length were chosen according to arterial measurements obtained by duplex scan. Plaque dissections and recoils causing stenosis of 30% or more, a peak systolic velocity ratio of 2 or more, or both were stented under duplex guidance. Arterial duplex examinations and ankle/brachial indexes were obtained before hospital discharge, within 1 month after the procedure, and every 3 months thereafter.

Results: Thirty-day survival was 100%. Local complications included one open exploration for expanding hematoma. Technical success was achieved in all cases. Placement of intraluminal stents was deemed appropriate in 23 (62%) of 37 cases. The 1-month patency and limb salvage rates were 100%. Preprocedure and postprocedure ankle/brachial indexes ranged from 0.3 to 0.9 (mean ± SD, 0.64 ± 0.16) and 0.64 to 1.2 (mean ± SD, 0.92 ± 0.15), respectively (P < .0001).

Conclusions: Duplex-guided balloon angioplasty seems to be a safe and effective technique that allows renal patients to experience continued limb salvage and relief from claudication without the risk of developing dye-induced acute renal failure. Other advantages include direct visualization of the puncture site, accurate selection of the proper size of balloon and stent, confirmation of the adequacy of the technique by hemodynamic and imaging parameters, and avoidance of radiation. Although this technique holds considerable potential, longer follow-up will help to fully evaluate its broader applicability. (J Vasc Surg 2005;42:1108–13.)

Duplex arterial mapping has been shown to be a reliable alternative to contrast arteriography before primary and secondary popliteal and infrapopliteal bypasses.1,2 This approach is particularly advantageous for patients with medical conditions (such as diabetes mellitus or pre-existing chronic renal insufficiency) that predispose them to an increased risk of developing contrast-induced renal failure. Acute renal insufficiency may develop in up to 31% of diabetic patients who undergo intravenous injection of contrast material.3-6 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 Moreover, 38% of diabetic patients with azotemia may develop contrast-induced renal failure.4

The newest generation of duplex scanners is capable of delivering high-quality images of the arterial wall and lumen while providing reliable hemodynamic parameters of the infrapopliteal arteries. In experienced hands, duplex scanners can be used to identify the exact location and magnitude of the occlusive disease process. The availability of these high-resolution scanners in our endovascular suite combined with our fairly extensive experience with duplex arterial mapping as a sole preoperative modality for infrapopliteal bypasses prompted us to investigate whether it was possible to perform balloon angioplasties in the lower extremities under duplex guidance alone. The concept of vascular ultrasound-guided therapeutic procedures is not new, and presently it includes thrombin injection for pseudoaneurysms of the femoral arteries, placement of inferior vena cava filters, and obliteration of large and incompetent saphenous veins with radiofrequency.7-10 Moreover, we have recently recognized the potential of this technique in guiding endovascular therapy for occlusive arterial disease in the carotid ar-
tery. Other investigators have published a series of ultrasound-guided balloon angioplasties for short superficial femoral artery (SFA) stenoses in highly selected cases; early results were acceptable but inferior to the ones obtained with standard techniques using contrast material. The purpose of this study was to analyze our early experience with 37 duplex-guided balloon angioplasties (DGBAs) in 28 consecutive patients with chronic renal insufficiency.

METHODS

Patients. This study included 28 patients with chronic renal insufficiency (serum creatinine levels $\geq 1.5$ mg/dL) who presented to our institution with lower limb ischemia over the previous 16 months. These patients underwent 37 DGBAs of femoropopliteal arterial segment. There were 24 cases (65%) of disabling intermittent claudication and 13 cases (35%) of tissue loss. Of these, 10 limbs had nonhealing ulcers, and the remaining 3 had gangrene. Eighteen (64%) patients were male. The age of the patients ranged from 58 to 92 years (mean ± SD, 74 ± 9 years). Concomitant risk factors included hypertension, diabetes, coronary artery disease, and smoking in 96%, 57%, 50%, and 29% of patients, respectively. Three patients (11%) were on chronic hemodialysis. Although none of these patients underwent preoperative contrast arteriography, they all had preoperative duplex arterial mapping performed by experienced registered vascular technologists using sonographic techniques previously described by our group. Duplex examinations showed severe stenosis in the SFA, popliteal artery (PA), or both in all cases. Severe stenosis was defined as a 70% diameter reduction or more measured on color and/or power image and confirmed by a peak systolic velocity (PSV) ratio step-up of 3 or more. No arterial occlusions were treated in this series.

Of 37 attempted DGBA procedures, 30 cases (81%) were primary, and the remaining 7 (19%) were performed for restenosis. Two patients had previously undergone failed ipsilateral bypass operations. One of these was a femoral-to-dorsalis pedis vein bypass, and the other was a femoral-to-popliteal vein bypass. We used the TransAtlantic Inter-Society Consensus (TASC) classification for morphologic stratification of femoropopliteal lesions.

During the study period, 15 femoropopliteal arterial bypasses were performed in an additional group of 14 patients with increased serum creatinine levels. The choice of bypass was primarily the surgeon’s preference.

Technique. Duplex probe manipulation and image optimization were solely performed by N.A.M. We used an ATL HDI 5000 scanner (Phillips Medical Systems, Bothell, Wash); the SonoCT feature was used in all cases. A linear 7- to 4-MHz probe inserted in a sterile plastic cover with coupling gel was used for insonation of the arteries that were 4 cm deep or less in most cases (34/37). The remaining 3 cases required a curved 5- to 2-MHz transducer to visualize deeper arterial segments, including the distal SFA and the above-the-knee PA. The length of the stenosis was measured with a linear 7- to 4-MHz probe. The length of the insonated arterial segment in one field is 4 cm. For lesions longer than 4 cm, we confirmed the length of the lesion by using skin markers to progress along the course of the insonated artery. The length of stenotic lesions in these patients varied from 2 to 45 cm (mean ± SD, 27 ± 15 cm).

All procedures but one (97%) were performed with patients under local anesthesia of the puncture site (an equal mixture of 1% lidocaine and 0.5% bupivacaine), and whenever indicated, light sedation was given during inflation of the balloon angioplasty catheter. The remaining patient opted for general anesthesia because of severe back pain when placed in the supine position.

The common femoral artery (CFA) was cannulated with a single-entry needle. The ipsilateral CFA was cannulated in 32 cases (86%), and the contralateral CFA was cannulated in the remaining 5 cases (14%). Still under duplex control, a short 6F Pinnacle introducer sheath (Terumo Medical Corporation, Elkton, Md) was inserted in an antegrade fashion into the SFA or retrograde in the external iliac artery (EIA) according to the proposed approach. Cannu-
translation and placement of a guidewire in the contralateral common iliac artery and EIA were accomplished with fluoroscopic guidance and the help of a 4F Flush Contra-directional catheter (Boston Scientific Corporation, Natick, Mass). Once the guidewire was visualized with sonographic means at the distal EIA/proximal CFA and a 6F Pinnacle Destination renal guiding sheath (Terumo Medical Corporation, Elkton, Md) was placed and parked in the ipsilateral EIA, the procedure was performed entirely with duplex guidance. The guidewire was directed into the SFA (Fig 2) and across the PA and was parked in the tibioperoneal trunk. To accomplish this, either a 5F Selective Bern catheter (Boston Scientific Corporation) or a 5F Angled Taper Glidecath (Terumo Medical Corporation, Somerset, NJ) was required in 20 (54%) of 37 cases. Next, the diseased segment was balloon-dilated under duplex visualization (Fig 3). Efforts were made to ensure that the length of the extracorporeal portion of the wire was minimally altered during catheter exchanges and that the lesion was still crossed by the wire as visualized by duplex scanning. Balloon diameter and length were chosen according to arterial measurements obtained by duplex scanning. We used Ultrathin (Boston Scientific Corporation) 5-, 6-, or 7-mm-diameter balloons. In cases with ipsilateral cannulation and proximal SFA stenosis, the sheath was withdrawn under ultrasonographic control, and its tip was placed into the CFA approximately 5 to 10 mm from the puncture site. This maneuver greatly facilitated angioplasty of the SFA origin.

After retrieval of the balloon angioplasty catheter, a detailed duplex examination of the entire treated segment was performed to identify areas of possible residual disease, plaque recoil (Fig 4), or dissection causing flow abnormalities. Two-plane (sagittal and transverse) duplex visualization improved identification of stenoses that could potentially be missed by uniplanar duplex scanning or contrast arteriography (ribbon effect). All areas of suspected defects were assessed by direct diameter-reduction measurement on color or power image, as well as by spectral analyses, including PSV and PSV ratios. Arterial stenoses causing more than a 30% luminal diameter reduction or a PSV ratio of 2 or more was considered significant and required placement of a self-expanding stent. These were also discharged under duplex guidance (Fig 5). Completion duplex examinations included visualization of all infrapopliteal arteries. Results of these examinations were compared with the ones obtained before the procedure in an attempt to identify possible embolization or thrombosis during balloon angioplasty.

Additionally, we recorded PA volume flow (PAVF) measurements before the procedure and at hospital discharge. Moreover, we measured PAVF before and after intra-arterial administration of 30 mg of papaverine hydrochloride. PAVF measurements were always taken three consecutive times for every time point. Mean PAVF values (±SD) and ranges were calculated.
Ten (27%) intraoperative completion arteriograms were performed in the beginning of this series for quality-assurance purposes. Of these, six were performed with Magnevist (Berlex Laboratories, Wayne, NJ) and four with Visipaque (Amersham Health, Princeton, NJ).

**Postprocedure evaluation and follow-up.** Arterial duplex scanning, pulse-volume recordings, and ankle/brachial indexes (ABIs) were routinely obtained before hospital discharge. Patients were advised to schedule follow-up visits in our outpatient office for clinical evaluation, arterial duplex scans, and pulse-volume recording examinations within the first month after discharge and every 3 months thereafter. Arterial patency at each time point was confirmed in the absence of a recurrent stenosis (≥70%) by duplex scanning.

**RESULTS**

**Technical success.** Immediate technical success of femoropopliteal angioplasties, as confirmed by completion color flow imaging and spectral analyses, was documented in all cases. Technical success was identified as patency of the angioplastomed femoral and/or PA segment with less than 30% stenosis and an absence of distal emboli.

**Intraoperative completion arteriography.** Of 10 arteriograms performed in the beginning of this series, discrepancy with completion duplex scan was found in 1 case (10%) in which a significant tibioperoneal trunk stenosis was missed by duplex examination because of poor visualization due to heavy calcification of the arterial wall. Conversely, there was a case (10%) in which the completion arteriogram failed to demonstrate distal SFA plaque recoil causing 60% stenosis identified on completion duplex scan. One (10%) of 10 patients who underwent intraoperative completion arteriography with 30 mL of gadolinium contrast had an increased creatinine level after the procedure (from 1.8 to 2.6 mg/dL).

**TASC classification.** There were 2 (6%) TASC class A lesions, 6 (16%) TASC class B lesions, and 29 (78%) TASC class C lesions in this series.13 Isolated popliteal stenoses were found in 3 cases (8%), and stenoses of the SFA were found in 5 cases (14%). Significant stenoses in both the SFA and PA were found in the remaining 29 cases (78%). Of the 29 cases with combined disease in the SFA/PA segment, 17 were contiguous lesions extending to the above-the-knee PA in 5 cases, behind the knee in 8 cases, and below the knee in 4 cases. In the remaining 12 cases, the distal lesions were not contiguous with the SFA and were located in the above-knee PA (n = 3), behind the knee (n = 4), and below the knee (n = 5). Of 34 diseased SFAs, 14 (41%) involved its origin. In six cases (16%), the SFA stenosis extended into the CFA.

**Stenting.** Placement of intraluminal stents (either stainless steel or nitinol self-expandable) was deemed appropriate in 28 (62%) of 37 cases. The reason for stent placement included plaque recoil in 16 cases (70%) and arterial dissection in the remaining 7 cases (30%). Technical adequacy was achieved after placement of a single stent in 15 cases, whereas 2 stents were necessary in 7 cases and 3 stents were necessary in the remaining case. Twenty-one stents were deployed in the SFA, and the remaining 11 were deployed in the PA above the knee.

**Intraoperative and early postoperative complications.** Local complications included one patient who required groin exploration for expanding hematoma. This was an obese patient who had a high femoral artery bifurcation. No distal emboli were detected on completion duplex scans. There were no early (30 days) postprocedural strokes, myocardial infarctions, or deaths in this series.

**Postoperative follow-up.** The mean follow-up in these patients was 6.5 ± 4.2 months (range, 1-19 months; median, 6 months).

**Patency and limb salvage.** The 1-month patency and limb salvage rates were 100%.

**Preprocedure and postprocedure ABIs.** Preprocedure ABIs were deemed reliable in 30 (81%) of 37 cases and ranged from 0.3 to 0.9 (mean ± SD, 0.64 ± 0.16). The remaining patients had either calcified noncompressible arteries (five cases) or nonaudible pulses (two cases). Postprocedure ABIs obtained before patient discharge ranged from 0.64 to 1.2 (mean ± SD, 0.92 ± 0.15; P < .0001). All patients with reliable ankle pressures demonstrated postprocedure ABI increases (mean, 0.27 ± 0.13; range, 0.08-0.63). In patients whose ABIs were unreliable before surgery, we compared the pulse volume amplitude tracings at the ankle level. The average amplitude of preprocedure ankle tracings in these seven cases was 4 ± 1 mm (range, 3-6 mm). The postprocedure average ankle tracing amplitude increased to 11 ± 3 mm (range, 6-14 mm). This increase was statistically significant (P < .01).

**Popliteal artery volume flow.** Preoperative and postoperative PAVFs are listed in Table I. Intraoperative PAVFs obtained after completion of angioplasty before and after intra-arterial administration of papaverine (30 mg) are depicted in Table II.

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<th>Table I. Comparison of mean popliteal artery volume flow (PAVF) obtained before angioplasty (column A) and at the time of hospital discharge (column B)</th>
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<th>Table II. Comparison of mean popliteal artery volume flow (PAVF) obtained immediately after angioplasty completion (column A) and after intra-arterial administration of 30 mg of papaverine hydrochloride (column B)</th>
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<td><strong>PAVF (mL/min)</strong></td>
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Procedure duration. DGBA duration ranged from 14 to 128 minutes (mean ± SD, 57 ± 25 minutes; median, 54 minutes). However, comparison of the mean duration of the first half of the cases (mean ± SD, 70 ± 25 minutes; median, 70 minutes) with the latter half (44 ± 17 minutes; median, 45 minutes) demonstrated a statistically significant improvement in procedure time (P < .001).

DISCUSSION

This study supports our belief that duplex methodology can be used to map the arterial disease process and to guide wires, sheaths, balloons, and stents for the treatment of superficial femoral and PA stenoses. Herein, we highlight several of the advantages provided by modern duplex scanners: (1) identification of the exact location of the stenotic lesion(s); (2) visualization of the guidewire in the arterial lumen; (3) selection of the proper size balloon and stent according to precise measurements of the vessel diameter and the extent of the lesion(s); (4) positioning of the balloon and stent regardless of motion artifacts because of continuous insonation of the target vessel; (5) relationship of the stent to the arterial wall; (6) visualization and balloon dilation of the SFA origin (Fig 6), which can be difficult with angiography, especially with a very large hypertrophied deep femoral artery and sheath overlap; (7) arterial imaging from approaches avoiding variable orthopedic prostheses; and (8) B-mode and spectral analysis confirmation of the adequacy of the procedure.

Conversely, we identified some important technical strategies that are worth describing. (1) The tip of the guidewire needs to be monitored at all times until it is parked a few centimeters beyond the most distal stenotic lesion. Often, this wire will enter a side branch, particularly proximal to the stenotic lesion, and will need to be redirected into the main arterial lumen (Fig 7). (2) At times a heavily calcified plaque may obscure visualization of the wire for a short distance (<3 cm). This may not prevent the successful completion of the procedure as long as gentle attempts at crossing this area are made and the guidewire is confirmed distally in the arterial lumen. The presence of a long circumferentially calcified segment that impedes visualization of the arterial lumen should discourage one from proceeding with duplex guidance alone. (3) The registered vascular technologist must be knowledgeable of the arterial anatomy of the lower extremities and must possess extensive experience in duplex mapping. The registered vascular technologist should not be hurried and should be allowed to use different scanheads and different approaches to optimize visualization of the target artery. Unless there is excellent visualization of the diseased arterial segment and the proximal and distal unobstructed segments, one should resist the temptation to proceed with duplex guidance and convert to arteriography. (4) The duplex monitor should be placed at a comfortable distance from the interventionist, who has to follow every step of the procedure.

An obvious advantage of using duplex scanners to guide interventional procedures is that one can actually visualize and puncture the target vessel with the same ease regardless of the antegrade or retrograde positioning of the entry needle. Blind attempts at cannulation of the femoral artery—particularly in obese patients, in small arteries, or in previously operated scarred groins—may be challenging.

Except for the five cases (14%) that required catheterization of the contralateral femoral artery, most cases in this series were performed without fluoroscopy. Clearly, our proposed approach is safer to the patient, the surgeon, and all personnel in the operating suite because it limits or eliminates radiation exposure. Duplex-guided procedures may become an important alternative for busy interventionists, who are frequently exposed to radiation. As endovascular procedures become an increasingly significant portion of the vascular surgeon’s practice, radiation exposure may impose a real health hazard that needs to be recognized and minimized. This problem is compounded with complex and lengthy endovascular procedures. As pointed out by Lipsitz et al,14 the deleterious effects of radiation exposure are cumulative and permanent, and the onset of signs and symptoms can be delayed.

Fig 6. B-mode image of a 6-mm Ultrathin balloon (black arrows) fully inflated across the superficial femoral artery origin (white arrows).

Fig 7. B-mode image of a 0.035-inch guidewire in the large superficial femoral artery branch (arrow).
The risks of dye administration during contrast arteriography in these often elderly diabetic patients with pre-existing renal insufficiency are well documented in the literature. Although it can be argued that 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, and specialty medical consultations. Conversely, we recognize that uncomplicated endovascular treatment of SFA stenoses can effectively be performed with minimal amounts of contrast material and short-duration radiation exposure.

The procedures were performed by three board-certified vascular surgeons. However, most (68%) were performed by the senior author (E.A.). There was no difference in results among all surgeons. Although the data presented herein suggest that our approach is feasible, effective, and safe, particularly for patients with renal insufficiency, we emphasize that a larger experience and a longer follow-up are required before a more liberal approach is proposed with this technique. However, one cannot underestimate the excellent visualization provided by modern duplex scanners: this greatly facilitated the performance of arterial mapping, as well as balloon angioplasty and stenting.

In summary, our preliminary data with DGBAs and stent placement show that this approach is feasible and effective in achieving excellent anatomic and hemodynamic improvement regardless of the extent of the stenotic lesion. Patients severely allergic to contrast material or those with renal insufficiency may benefit from the proposed approach.

REFERENCES