An Effective Guidewire Looping Technique for the Recanalization of Occlusive Segments of Infrapopliteal Vessels

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Objective: To determine the efficacy, safety and primary follow-up results of a guidewire looping technique for the treatment of infrapopliteal arteries.

Materials and Methods: From October 2006 to May 2008, an intraluminal angioplasty of the infrapopliteal arteries was attempted in 200 consecutive patients. Altogether, 417 infrapopliteal lesions, with lengths varying from 2 cm to 32 cm, were treated as part of this study, including 305 lesions in the anterior tibial arteries, 89 in the posterior tibial arteries, and 23 in the peroneal arteries. The 'U'-shaped guidewire technique was attempted in 393 lesions from 361 limbs. The tip of a hydrophilic 0.035-inch guidewire was formed into a 'U' shape with the aid of a 4-Fr catheter and collateral branch vessel to recanalize the completely occluded long segment lesions.

Results: A successful angioplasty with at least one artery recanalized directly to the malleolar or dorsal foot was achieved in 322 limbs (89%). The looping technique had a success rate of 90% (352 of 393 lesions). After the procedure, the rest pain was relieved in 58 of 69 patients, while 207 of 245 limbs (85%) showed improvement for intermittent claudication. Complete wound healing was noted in 21 of 54 patients, while 20 of 54 patients showed an improvement in the wound size or depth. A total of 38 major immediate procedure-related complications were noted, including retroperitoneal hematoma, distal emboli, and vessel rupture.

Conclusion: The results of this study suggests that the guidewire looping technique is a safe and effective method for the recanalization of the occluded lesions in infrapopliteal vessels.

Symptomatic lower limb ischemic disease is characterized by a malignant natural history and is predominantly caused by diabetes mellitus. As a result, a significant number of patients eventually require a limb amputation. Although Dotter and Judkins (1) described three cases of percutaneous transluminal angioplasty (PTA) of the tibioperoneal trunk in their classic 1964 paper, and the number of angioplasty procedures performed in iliac, femoral, and popliteal vessels has increased several folds in the past decade, experience with dilatation of the infrapopliteal vessels has been limited. Due to the recent developments in balloon catheters, there has been a significant shift toward lower limb revascularization using endoluminal techniques over the last five years (2). Stenotic lesions of the infrapopliteal arteries, either in isolation or in combination with iliac-femoral-popliteal axis disease, can be treated with PTA (3–5). However, direct endovascular access over the occlusive lesion with a straight tip guidewire is not always possible. We found that advanced guidewires with a U-shaped tip could effectively cross the long or multi-occlusive segment smoothly and go into the distal outflow vessel. Although there are a number of reports describing the use of PTA for the treatment of occlusive lesions in the infrapopliteal arteries, few studies mentioning this guidewire looping technique placed a strong emphasis on the procedure (6).

The aim of the present study was to determine the efficacy, safety and primary follow-up results of the guidewire looping technique in the PTA of infrapopliteal arteries.

MATERIALS AND METHODS

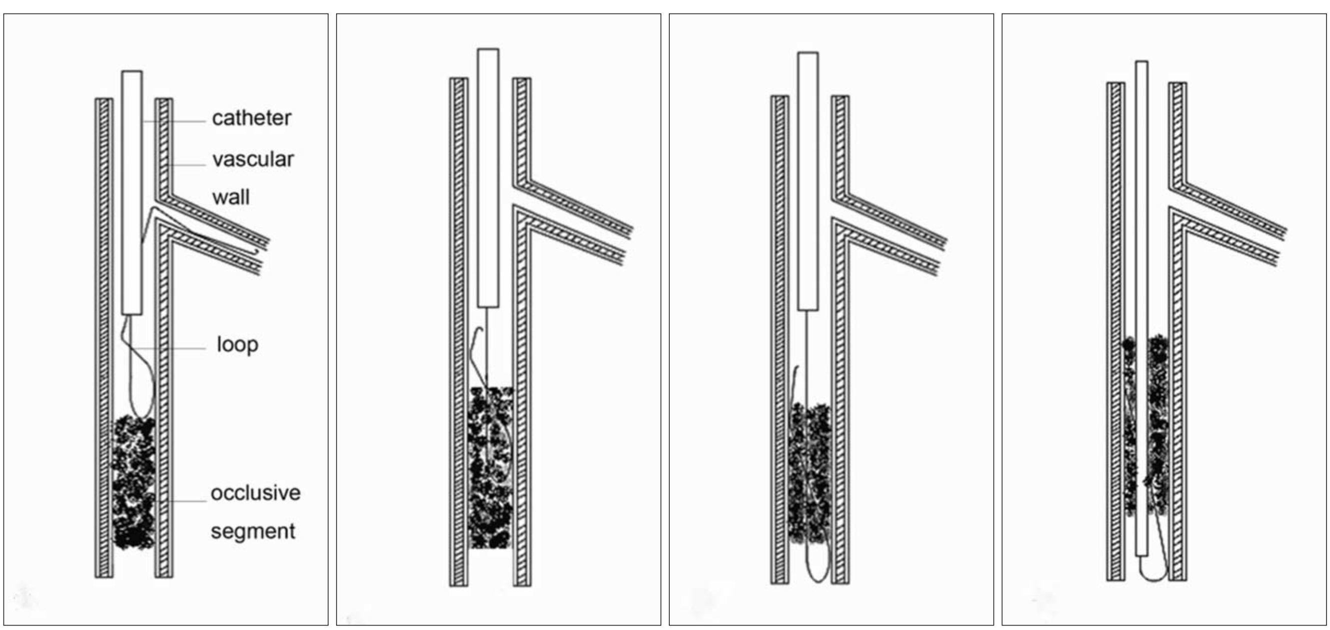
Patients

From October 2006 to May 2008, PTA of the infrapopliteal arteries was attempted in 386 limbs (200 consecutive patients, 243 procedures) of patients presenting with limb ischemia. In 143 patients, infrapopliteal PTA was performed on both legs. The patient ages ranged from 56 to 89 years (mean 76 years) and there were 118 women and 82 men. A total of 182 patients (91%) were diabetics, 147 (74%) had hypertension, 45 (23%) had coronary artery disease, 16 (8%) had cerebral vascular disease, and 41 (21%) were smokers. Clinical symptoms included rest pain in 69 (18%) patients, intermittent claudication in 245 (64%), ulcers in 54 (14%), and gangrene in 18 (5%) limbs. The mean (SE) ankle brachial pressure index (ABI) was 0.53 ± 0.17 (range 0.36–0.81) before the intervention.

We generally defined arterial abnormalities as follows: foot pulse reduced or absent, ABI < 1 (in the absence of arterial calcification), or duplex scanning revealing stenosis > 50% of the vessel lumen. If two of the three criteria are confirmed, then a lower extremity MR angiography (MRA) was performed to confirm these abnormalities and evaluate the vasculature and collateral compensation in all patients who were supposed to receive PTA treatment.

All MRI examinations were performed on a 3.0T MR system (Achieva 3.0 T, Philips Medical Systems, The Netherlands). Automatic table movement bolus chase 3D contrast-enhanced MRA was employed to perform a four-station protocol (lower abdomen-thigh-lower leg-foot) by using an integrated whole body coil with additional infragenual cuff-compression (end pressure of 50 mmHg) during the MRI examination. A biphasic injection of gadodiamide was chosen at an initial volume of 20 ml and at a flow rate of 2.5 ml/s, and was immediately followed by a second volume of 20 ml at a flow rate of 2.0 ml/s. For all stations, the 3D mobiflex-3.0T sequence in the coronal slice order was used with the following parameters: TR = 3.5–4.4 ms, TE = 1.28–1.64 ms, flip angle = 20°, field of view = 375 mm, voxel size = 0.98.

Antegrade or retrograde puncture of the femoral artery was decided according to the MRA results and discussed between the two vascular interventional radiologists. Digital subtraction angiography (DSA) was then performed, and a



A B C D

Fig. 1. Diagrams showing transluminal angioplasty technique.
A. We first inserted hydrophilic guidewire into proximal branch and then made ‘U’ shape loop by rotating and advancing guidewire continually.
B, C. Loop guidewire was advanced into and over occlusive segment of vessel.
D. Catheter was crossed over occlusive segment along guidewire.

subsequent PTA procedure was performed if necessary.

Techniques of Transluminal Angioplasty

The procedure was performed under local anesthesia. The antegrade puncture of the femoral artery was used in all but 33 limbs. In those 33 limbs, PTA was performed with a cross-over technique from the contralateral side because of the severe stenotic lesions in the ipsilateral puncture site or extreme obesity of the patient. All interventions were performed through a 6 Fr access system (Terumo Co., Tokyo, Japan). A 4-Fr vertebral catheter (Cook, Bloomington, IN) was subsequently introduced and an angiography was performed. Heparinization was instituted to a targeted activated coagulation time of 250 to 300 seconds. The tip of the catheter was placed at the proximal end of the occlusive vessel under the guidance of a road map. The outflow tract in the distal end of the occlusive lesion was an indication that an angioplasty was necessary. We used a low friction hydrophilic 0.035-inch guidewire (Terumo Co., Tokyo, Japan) for the recanalization of the total occlusions. The tip of the guidewire was shaped into and allowed to form a 'U' shape with the aid of a 4-Fr catheter and collateral branch vessel in the proximal part of the occluded lesion. Then, we advanced the guidewire and broke through the occluded vessel. The 'U' shape of the guidewire could ensure a wider profile, thus preventing the guidewire to exit the arterial wall or enter into the subintimal area. The 4-Fr vertebral catheter was then advanced over the wire (Fig. 1). After performing an immediate angiography and confirming a definite outflow tract, the 0.035-inch hydrophilic guidewire was replaced with a 0.014-inch Skipper exchange guidewire (Skipper Deep; Invatec, Brescia, Italy). Hemi-compliance low-profile balloons (Amphirion Deep; Invatec, Brescia, Italy) with a balloon length of 80 or 120 mm and a diameter ranging from 2.0 to 3.5 mm were used for dilating the occluded vessel. The dilating pressure ranged from 6 to 10 atm and was maintained for three minutes. No prophylaxis against vasospasm was used. Immediate postangioplasty angiograms were obtained in all cases. Intravenous heparin (a bolus of 4,000 IU followed by 1,000 IU) was injected to maintain an activated clotting time of 250 to 300 seconds during the procedure. An additional 5,000 IU of low molecular weight heparin was administered subcutaneously every 12 hours for three days after the procedure. Upon ambulation, the patients were to receive life-time antiplatelet (Aspirin, Bayer Co., 100 mg daily) treatment.

Table 1. Lesion Characteristics

Characteristics of Limbs Treated with Infrapopliteal Angioplasty	Value
Indications	
Claudication	245 (64%)
Rest pain	69 (18%)
Ulcer	54 (14%)
Gangrene	18 (5%)
Lesion location	
Anterior tibial artery	305 (73%)
Posterior tibial artery	89 (21%)
Peroneal artery	23 (6%)
Lesion	
Stenosis	24 (6%)
Occlusion	393 (94%)
Lesion length	
< 10 cm	123 (29%)
> 10 cm	294 (71%)
Outflow tract	
Without outflow tract	179 (43%)
With outflow tract	238 (57%)
No. of procedures per limb	
One	343 (89 %)
Two	43 (11%)
Technique success	374 (90%)
Anterior tibial artery	277 (91%)
Posterior tibial artery	77 (87%)
Peroneal artery	20 (87%)
Adjunct intraluminal PTA procedures	
SFA and/or popliteal level	142
< 10 cm	128 (90%)
> 10 cm	14 (10%)

Note.— Data represent sample size, data in parentheses are percentages. PTA = percutaneous transluminal angioplasty, SFA = superficial femoral artery

Technical success was defined as at least one anterior or posterior tibial artery with less than 50% residual stenosis that could be recanalized to the malleolar or dorsal foot along with no immediate severe complications. Clinical success was defined in the wound group as complete healing of ulcers or dry and painless toe gangrene. In the intermittent claudication or rest pain group, success was defined as significant improvement in terms of distance walked or relief from rest pain for at least six months.

A total of 417 occluded or severe stenotic lesions were treated by PTA. Among the 386 limbs treated, there were 305 lesions of the anterior tibial artery, 89 lesions of the posterior tibial artery, and 23 lesions of the peroneal artery (Table 1). The lesion length varied from 2 to 32 cm, including 294 (71%) lesions that were > 10 cm and 123 (29%) lesions that were < 10 cm ($p < 0.0001$). Altogether, 238 (57%) lesions had an obvious outflow tract, whereas the rest did not.

Definition and Follow-Up

The patients were followed by clinical examinations at one, six and twelve months after the endovascular treatment. MRAs were supposed to be performed at six months in all patients. For those who were reluctant to undergo an MRA follow-up, a Doppler ultrasound examination was performed instead. At each follow-up examination, pain and wound healing were evaluated and palpated leg pulses were recorded. The visual analogue scale method was used to compare the pain levels before and after the procedure. Pain relief was considered to have occurred if patients marked a 0.2-cm drop in pain level on a 0 to 10-cm scale.

RESULTS

Immediate Technical Success Rate

In this study, a technically successful PTA in at least one artery that could be recanalized directly to the malleolar or dorsal foot was achieved in 322 limbs (89%) (Fig. 2). Altogether, 374 of 417 (90%) infrapopliteal occluded or severely stenotic lesions were successfully recanalized. Technical failure was noted in a total of 43 lesions in 39 limbs. The loop technique was attempted in 393 of 417 lesions (94%) in 361 limbs, and the technique success rate attained 90% (352 of 393 lesions). In certain cases, the loop guidewire could not cross over the occlusion segments because of severe calcification; this situation occurred in 41 lesions longer than 10 cm. Vessel rupture occurred in 19 segments and we treated 142 compound stenoses or occlusions in the iliac-femoral-popliteal axis arteries of 98 patients, which were subsequently followed by the implantation of 28 self-expanded stents.

Early Complications (Within 30 Days)

There were a total of 38 major immediate post-procedure complications that were noted. One patient suffered a retroperitoneal hematoma four hours after the procedure, which required an emergency surgical intervention. Distal emboli were found in 24 vessels (6%), all of which were treated with urokinase and thrombosuction. Ischemia did not improve in one patient, and he subsequently required a below-ankle amputation two weeks later (Fig. 3). Vessel rupture was identified in 19 of 393 (5%) segments of 19 limbs because the guidewire perforated the wall of the vessel. For these patients, the heparin was immediately balanced out with protamine sulfate, and in 15 of these limbs, a successful intraluminal angioplasty was eventually performed. No other treatments were required for the remaining four limbs from the four patients, but their symptoms of limb ischemia did not improve. There were 46 (12%) minor local dissections at sites after the dilatation, of which 21 were left untreated because no retrograde flap was detected by the antegrade angiography. The remaining serious detected intimal flaps were treated by re-dilation with a balloon of the same diameter, but at a higher pressure (an additional 1–2 atm). Ecchymoma around the puncture site was identified in 23 patients. They were treated with physical therapy. Fifty-five patients suffered from ipsilateral limb edema secondary to distal reperfusion. Three patients were found to have slightly elevated creatinine levels. No deaths were directly attributable to the procedures.

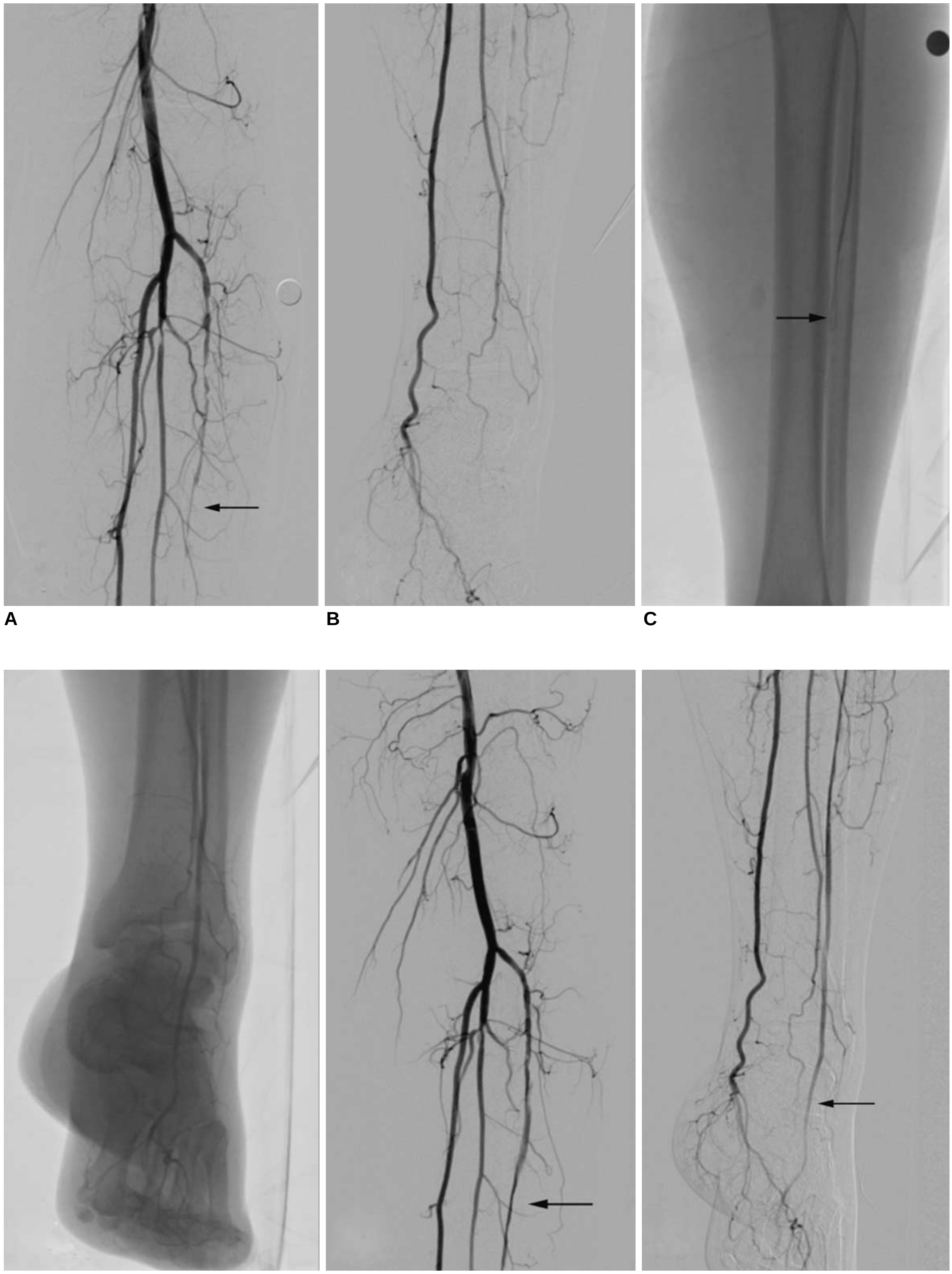
Clinical Success and Follow-Up MR Angiography

The mean follow-up period for this study was 10.5 ± 6.2 months (range: 1 to 12 months). Altogether, clinical success, including improvement of intermittent claudication or rest pain and wound healing, was achieved in 186 of the 200 (93%) patients. After the procedure, rest pain was relieved in 58 of 69 (84%) limbs and 207 of 245 (85%) limbs showed improvement for intermittent claudication. Complete wound healing was noted in 21 of 54 (39%) limbs and 20 of 54 (37%) limbs showed improvement in the wound size or depth. Of these cases of improvement, two developed a new wound six months after the PTA. A repeat PTA on the same leg was performed on 43 limbs in 35 patients. In the healed/improved group, no amputations or surgical revascularizations were required. Twenty-two patients had subsequent minor leg amputations, but the level of amputation was lower than previously estimated. The non-symptomatic patients did not undergo a diagnostic angiography during the follow-up period. MRA data could be obtained from 144 patients, while 35 patients underwent a Doppler ultrasound examination follow-up. The MRA follow-up at six months found re-stenosis (stenosis $\geq$ 50%) in 34 of 264 segments, but the majority of these patients did not show any symptoms.

DISCUSSION

Peripheral artery occlusive disease is estimated to occur in 3% of people aged 40–59 years and in 20% of people over 70 years, as documented by noninvasive testing (3, 4). Percutaneous endovascular procedures are increasingly applied to treat symptomatic peripheral artery occlusive disease. Despite the fact that advances in balloon catheters have made the infrapopliteal PTA procedure easier than before for long or multi-segment occluded vessels, it is still difficult for the catheter to cross over occluded segment(s).

The first step of successful PTA is inserting the guidewire through the occluded site. If the occluded vessel is



A B C D E F

Fig. 2. 67-year-old man with more than 10-year history of diabetes mellitus presented with symptoms of limb ischemia.
A, B. Lateral lower limb angiogram revealed long segment of occlusive disease in anterior tibial artery along more than 15 cm, with faint run-off tract (arrow).
C. Plain film showed head of hydrophilic guidewire (arrow) forming loop when passing through occlusive segment through 4-Fr vertebral catheter.
D. Fluoroscopic angiogram demonstrated run-off tract indicating true lumen process.
E, F. Immediate angiogram performed post-procedure showed restoration of anterior tibial artery with straight-line flow to pedal arch. Residual stenosis was less than 30% (arrows).

Fig. 3. 69-year-old women with 15-year history of diabetes mellitus presented with gangrene in three to five toes of her right foot.
A, B. Lateral lower limb angiograms reveals long segment of occlusive disease in anterior (arrow) and posterior tibial arteries.
C, D. Plain films shows head of hydrophilic guidewire forming loop and passing through occluded segment with 4-Fr vertebral catheter and long balloon dilation of recanalized artery.
E, F. Immediate angiograms performed post-procedure show restoration (arrow) of anterior tibial artery, but distal dorsal artery was embolized and subsequent thrombolysis did not work. Patient ultimately underwent below ankle amputation.

relatively short, it is easier for the guidewire to cross over to the distal true lumen simply with a straight head. However, we often encountered longer occluded vessel in diabetic patients. Under this circumstance, the straight tip guidewire could easily perforate into the intima or outside the arterial wall and eventually result in dissection or vascular rupture. Thus we remolded a 'U' shape loop out of a 0.035-inch hydrophilic guidewire and made the guidewire and a 4-Fr catheter cross the occlusive segment. Next, the guidewire was withdrawn and an angiography was performed to confirm that the catheter was in the true lumen. Following this, a 0.014-inch Skipper guidewire was exchanged for the balloon angioplasty. The support power of the guidewire was important when crossing the occluded vessel. The diameter of the compatible guidewire for the new infrapopliteal balloon catheter was 0.014 inches, which provided insufficient support compared to the commonly used 0.035-inch hydrophilic guidewire. In the early stages, we nevertheless tried to cross through the lesion with the Skipper guidewire, but the tip was too soft to cross over.

There are two methods for remolding the 'U-shaped' loop. The first method involved the use of a remoldable guidewire (Terumo Co., Japan). We can remold the tip to a 'J' type in advance and then insert the catheter. This 'J' type could recover in the larger diameter vessels such as the superficial femoral artery. The guidewire and the catheter were advanced as one entity to the infrapopliteal artery. This method was sometimes not effective because the remolded guidewire was inserted into the infrapopliteal target vessel with difficulty, especially into the anterior tibial artery. The other method relies on assistance from the catheter and vascular branch. Under most circumstances, we can first insert the hydrophilic guidewire into a proximal branch and then make the 'U-shaped' loop by continually rotating and advancing the guidewire. When using the 0.035-inch stiff guidewire to penetrate long occlusion lesions, we generally looped the head wire into a 'U' shape by letting the head of the wire enter one of branches and then twisting the wire to form the loop. This technique helps to guarantee that the guidewire stays in the arterial lumen, prevent the guidewire from perforating the vessel, and hence reduce damage to the vessel wall during advancing. This technique also provides strength when penetrating an organized thrombus or calcified plaque as well as reduce the likelihood that the wire will enter the subintima as occurs when using the 'J-shaped' guidewire head. This intraluminal angioplasty technique allows us to reduce the thrombosis occurrence and also provides a better long-term patency of the recanalized vessel compared to the subintimal angioplasty, according to our study (5, 7). However, this technique may have a high manipulation requirement and result in a somewhat higher vessel perforation rate (5%). Careful advance must be maintained to prevent the guidewire from perforating the proximal vascular branch.

The size of the loop is very important. We should regulate the size with the catheter in time. Sometimes we need to rotate the guidewire to better facilitate its passing through the lesion. The loop tip of the guidewire should be kept straight before it arrives at the dorsal artery of the foot or arteria plantaris, because its diameter is close to that of the guidewire (Fig. 3). Severe hemorrhage could occur if one forcedly crosses the guidewire through these vessels.

Hemorrhagic complications were sometimes serious, but few required surgical intervention. Axisa et al. (8) report that a emergency surgical intervention was required after 31 of 1,377 procedures (2%) with acute limb ischemia and hemorrhagic complications. In our group, only one patient with a retroperitoneal hematoma required emergency surgical treatment. The hemorrhage caused by infrapopliteal vessel perforation required no further treatment and no calf hematoma was found.

Distal embolic events may be inevitable in the procedure of recanalization of an occluded vessel. Distal embolization of a plaque or thrombus may cause organ ischemia following percutaneous peripheral interventions, especially in the superficial femoral or iliac artery. This event may occur at various phases of intervention such as guidewire crossing, balloon angioplasty, stent deployment, and so on (9). Thrombolytic or thrombosuction therapy was usually effective and amputation was performed in only one patient after an angioplasty because of distal limb ischemia. This rate is consistent with the report by Axisa et al. (8). To date, stent deployment below the knee is rare; Lam et al. (9) monitored the whole procedure during a superficial femoral artery intervention and found that embolic signals were noted in every patient during wire crossing, angioplasty, stent deployment, and atherectomy. However, patency was restored angiographically after thrombolysis. Despite the frequency of these events, only one patient developed an angiographically and clinically significant embolization. In our patients, distal embolic events were noted angiographically in 24 vessels, however only one patient suffered from significant ischemia of a limb requiring below-the-knee amputation.

An ipsilateral antegrade common femoral artery (CFA) puncture is usually preferred to a contralateral retrograde femoral access for the below-the-knee PTA. In our group, procedures on all but 33 limbs were performed with an antegrade puncture of the femoral artery. Antegrade puncture refers to the placement of an angiographic needle in the CFA in the direction of arterial flow. The puncture is made in the skin above the inguinal ligament, but the tip of the needle should always enter the CFA below the inguinal ligament. This procedure allows for the insertion of a vascular sheath for balloon angioplasty of the superficial femoral and/or popliteal arteries (10). Because of the frequent difficulty with providing sufficient manual pressure at the puncture site, an antegrade puncture is complicated by a high number of local bleeding complications, including retroperitoneal hematoma (11). Hemostasis of the puncture sites at the end of the procedure in all of our patients was achieved by manual compression. Arterial access can be complicated by a 'hostile groin' (scarring, obesity, or previous failed CFA puncture) (12). An antegrade puncture is technically more difficult than a retrograde puncture. It is a challenging procedure with a learning curve for the interventional radiologist (13). A high puncture (above the inguinal ligament) is associated with increased incidence of groin hematoma and retroperitoneal hemorrhage, whereas a low puncture is associated with increased incidence of arteriovenous fistula and pseudoaneurysm formation (14, 15). A fluoroscopy is a helpful technique in guiding the arterial puncture towards the mid-femoral head. In obese patients, the abdominal fat should be retracted to facilitate the puncture (10). Local bleeding may cause ecchymoma, which could be relieved via physical treatment. To date, femoral artery closure devices such as the Angio-Seal collagen plug and anchor device have been approved and shown to benefit patients after femoral artery catheterization. Only a few studies in the literature have examined such closure devices of a post-antegrade puncture (11, 16–18). These vascular closure devices may be a safe, efficient and uncomplicated means of achieving arteriotomy closure of a post-antegrade puncture.

In conclusion, in our experience, PTA of infrapopliteal vessels is effective in treating infrapopliteal arterial occlusive disease, while also being associated with a low risk for major medical and surgical complications. Based on our findings, the guidewire looping technique is safe and effective for the recanalization of occlusive segments of vessels. As far as we know, this paper is the first report on this technique applied to below-the-knee vessels.

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