TAMI Technique: Tibiopedal Arterial Minimally Invasive Retrograde Revascularization

A novel approach to revascularization in patients with critical limb ischemia.

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The prevalence of peripheral vascular disease (PVD) is on the rise. It is estimated that the number of patients living with PVD in the United States (US) and other Western countries will reach 22 million by the year 2030. This estimate is based on a number of large-scale trials conducted in the United States and in other Western countries.[1-5] The complexity of PVD and the significant comorbidities affecting those with critical limb ischemia are major limiting factors in referring patients to surgery. This is one of the main reasons that endovascular therapy is becoming the primary default strategy for revascularization. However, endovascular therapy has its own limitations, ranging from access site complications to renal impairment related to contrast utilization. We are constantly looking for new ways to improve safety and decrease the risk involved in these procedures. The tibiopedal arterial minimally invasive retrograde revascularization (TAMI) technique was developed to address these difficulties. This article describes this novel technique and its applicability.

Figure 1. Nonhealing ulcer at presentation.

CASE PRESENTATION

A 69-year-old woman was admitted to our institution with ongoing rest pain and a 3-year history of a nonhealing ulcer of the right forefoot that had progressed to its current state (Figure 1). Six years previously, she underwent amputation of all five toes on her right foot due to gangrene. The patient had multiple comorbidities, including diabetes mellitus (DM) type II, hypertension, ischemic cardiomyopathy, and morbid obesity. Her most recent left ventricular ejection fraction was measured at 30%. Magnetic resonance imaging of her

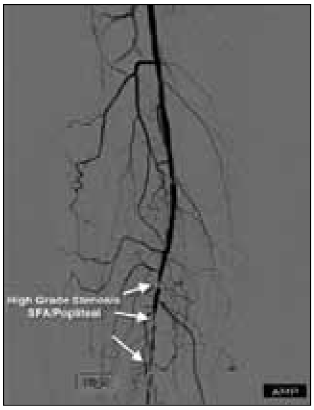

Figure 2. Angiography depicting the multilevel high-grade stenosis within the distal SFA and popliteal artery.

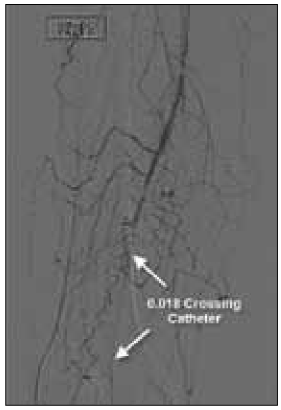

Figure 3. Angiography depicting a 0.018-inch crossing catheter advanced over a 0.014-inch wire.

foot revealed evidence of osteomyelitis involving the first metatarsal. Her vascular exam was abnormal, with absent bilateral pedal pulses and ischemic ulcer of the right forefoot. Handheld Doppler examination revealed faint monophasic Doppler pulses in the right dorsalis pedis and posterior tibial arteries. The baseline ankle-brachial index was measured at 0.36 on the right and 0.56 on the left.

The initial peripheral angiogram was performed via conventional right common femoral artery (CFA) retrograde access. Multiple images were obtained during the procedure. These showed severe right superficial femoral (SFA) and popliteal artery disease, including total occlusion of the right midpopliteal artery that reconstituted in the distal segment of the popliteal below the knee (Figures 2 and 3). The tibial runoff was poor and not well visualized via the antegrade contrast injection, and good tibial reconstitution proximally was not evident. There was evidence of reconstitution of the posterior tibial and anterior tibial above the ankle on the right.

During the procedure, the patient became agitated, short of breath, and became hypoxic, requiring medical intervention including 100% oxygen delivered by a venting mask. Initial evaluation showed that the patient developed hypertensive urgency complicated with flash pulmonary edema. This was immediately addressed and stabilized. The procedure was stopped early. In addition, the access site developed a moderate-sized hematoma after sheath removal. No other vascular access complications occurred.

Based on the angiographic findings, we felt femoral-popliteal bypass would be the best option, due to the patient's distal SFA and popliteal disease. Vascular surgery was consulted. Due to her multiple comorbid conditions and the lack of tibial runoff visualization, it was deemed that she was not a surgical candidate.

Upon receiving this information, we reviewed the patient's diagnostic peripheral angiogram. Based on the arterial disease findings and the cutaneous ischemic breakdown, we considered brachial versus retrograde tibial access for the interventional approach. A brachial approach would have been feasible but would have limited potential treatment of below-the-knee vessels due to device lengths. A decision was made to proceed with TAMI.

The TAMI technique will be described in a stepwise fashion. It can be considered for patients who are not candidates for vascular bypass surgery or conventional retrograde or antegrade CFA access and may be used in scenarios in which no other alternative access is feasible.

STEPWISE INTERVENTIONAL COURSE

Step 1: Patient Placement

The patient was placed on the angio suite table with a supporting mattress that allowed her to sit at a 45° angle (Figure 4). This position was unique; we learned from our previous diagnostic angiogram that the patient is unable to lie flat due to back pain and shortness of breath. Once the patient was comfortable and showed stable vital signs for 10 minutes, we proceeded with preparation for TAMI. During the TAMI procedure, the patient was prepped and draped in the usual sterile fashion. She was positioned feet first on the angio suite table; her feet were placed at the location where the head is normally positioned during a peripheral angiogram with conventional retrograde CFA access.

The target limb—the right lower extremity—was left exposed from the groin to the toes. Sterile towels were then placed over the leg so that it could be exposed and recovered as needed during the procedure. Keeping the target limb fully exposed and sterile allows operators to obtain multiple access sites as needed and

Figure 4. Table setup with the patient elevated at a 45° angle.

Figure 5. Ultrasound short-access view of the posterior tibial artery showing the relationship between the tibial artery and veins.

to use ultrasound-guided access and intervention without limitations. Also, this provides an option for readily accessible antegrade access throughout the procedure, if it is urgently needed.

The angio table controls were kept in the conventional position, making table maneuvering readily available at all times. The controls could be moved to any location on the angio table, depending on the position of the operator.

Step 2: Access

Based on the cutaneous angiosome of this patient, it appeared that both the plantar artery and the dorsalis pedis artery distributions were involved, which was consistent with the angiographic finding of the SFA/popliteal occlusion. We believed that revascularization of the major inflow to the tibiopedal vessels would provide sufficient inlying blood supply and nutritional support, which is crucial for healing in patients who present with deep wounds.

Due to its mostly straight nature, the posterior tibial artery was chosen as the major access site for revascularization from the retrograde approach. Antegrade access was avoided due to the previous complications mentioned earlier. The seriousness of tibial access in scenarios where a complication here could mean loss of limb is acknowledged, but our patient did not have alternative options that would not lead to amputation.

The access approach was performed in the following fashion. Initially, a hockey stick ultrasound probe was used to visualize the posterior tibial artery above the ankle in both short- and long-axis views, and a somewhat healthy patent segment was identified as a target access point for sheath placement. Once a target segment was selected, ultrasound guidance was used to advance our 21-gauge access needle (Cook Medical, Bloomington, IN), which was visualized directly as it entered the tibial arterial wall while the tibial veins surrounding the tibial arteries were carefully avoided. (Figure 5) Once the percutaneous needle was in the tibial artery (Figure 6), a 0.021-inch wire was advanced, and the needle was exchanged for a 4-F Precision Sheath (Terumo Interventional Systems, Somerset, NJ) (Figure 7). The sheath was then flushed (Figure 8), and a retrograde tibial angiogram (Figure 9) was performed to confirm intra-arterial presence, obtain clear retrograde tibial arterial mapping, and reconfirm the target lesion for revascularization.

Figure 6. The access needle with arterial blood flow.

Step 3: Successful Arterial Cannulation

Successful arterial cannulation results in bright blood return. Depending on the degree of disease, pulsatile blood flow may not be present. Also, on rare occasions, we are forced to rely on visual confirmation of arterial access by ultrasound imaging of the access needle and wire within the target tibial artery, followed by retrograde selective angiography for final confirmation.

Step 4: Access Wire Introduction

In many diseased tibial arteries, a regular 4-F sheath may potentially occlude the artery completely and create blood flow stagnation, which is associated with increased risk of acute thrombus formation. We have adopted a technique of placing a 4-F micropuncture sheath or dilator, which has a significantly smaller

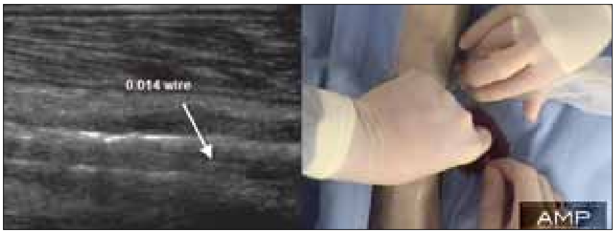

Figure 7. The 0.014-inch wire is advanced through the tibial artery. Note the ultrasound probe following the wire.

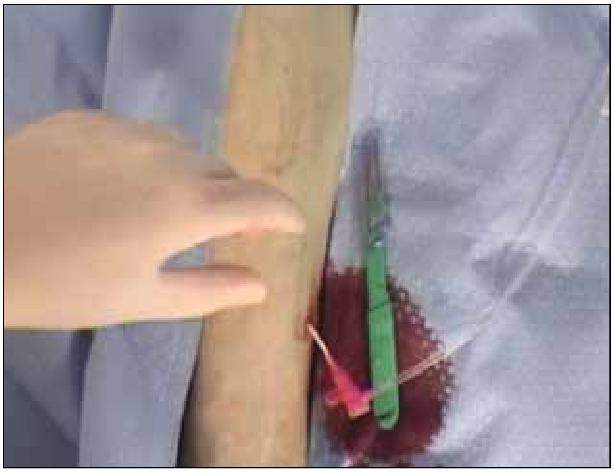

Figure 8. Retrograde sheath placement after pharmacological therapy.

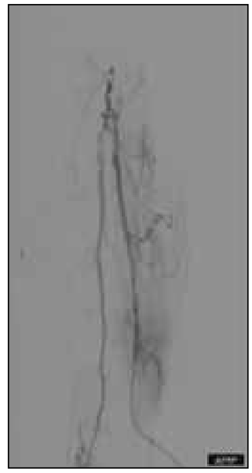

Figure 9. Final contrast injection through the side arm of the sheath.

Figure 10. The use of retrograde orbital atherectomy through the tibial sheath.

outer diameter, allowing blood flow around the sheath despite presence of vasospasm or plaque. During the transient placement of the micropuncture dilator or sheath, the operator gives intra-arterial nitroglycerin (400 µg) and heparin (80 units/kg, our institutional protocol for tibiopedal interventions) and performs the initial diagnostic images. An activated clotting time (ACT) of between 200 to 250 seconds was maintained. The ACT was checked at 20-minute intervals to maintain a higher ACT while working in the tibial vessels to avoid the risk of thrombosis. Also, a 10-minute interval was initiated after the first nitroglycerin dose. Typically, we use an intratibial nitroglycerine injection of 200 to 400 µg, based on blood pressure tolerance.

Both heparin and nitroglycerine create a transient burning sensation in the ankle and foot area immediately after intra-arterial injection. Patients should be warned about the sensation before administration of these medications. Once these two drugs have been administered, the likelihood of acute thrombus or severe spasms is minimized during tibial access interventions.

Both the Cook Medical and Terumo Interventional Systems micropuncture wires have a smooth wire transitional zone in their tips. The transition is short, allowing for the stiff wire portion to support the advancement of the sheath.

We have adopted the use of ultrasound-guided wire advancement during the initial phase of sheath placement. This achieves two purposes: First, we can maintain the wire tip in the true lumen, away from the subintimal space; second, real-time visualization allows for maneuvering of the wire across plaques and high-grade stenosis.

Step 5: Sheath Insertion

In elderly patients with advanced PVD and venous disease, the skin tends to be thick, and advancing the sheath might be difficult. In these cases, the operator can create a small incision to facilitate advancing the sheath while avoiding injury to the vessel.

Step 6: Intra-arterial Sheath Confirmation

Under fluoroscopy, contrast injection confirmed the intraluminal position of the sheath. Usually, the operator injects 5 to 10 mL of diluted contrast (50% contrast, 50% saline). Ultrasound is another method for confirming intra-arterial sheath position by injecting agitated saline.

Step 7: Revascularization Strategy

Choosing the modality of therapy depends on the lesion to be treated. For example, in patients with chronic total occlusions, different crossing modalities may be used, such as a wire-and-catheter technique or dedicated crossing devices that fit through 4-F sheaths. In this case, a 0.018-inch CXI catheter (Cook Medical) with a 0.014-inch Runthrough wire (Terumo Interventional Systems) were employed.

Once the lesion is crossed, the operator chooses the modality of therapy. For this patient, orbital atherectomy (Cardiovascular Systems, Inc., St. Paul, MN) through a 4-F Precision sheath was successfully used (Figure 10). Angioplasty using a low-profile balloon that fit through the 4-F Precision sheath was employed (Figures 11 and 12). In this case, we used a low-profile 0.014-inch system Ultraverse balloon (Bard Peripheral Vascular, Tempe, AZ).

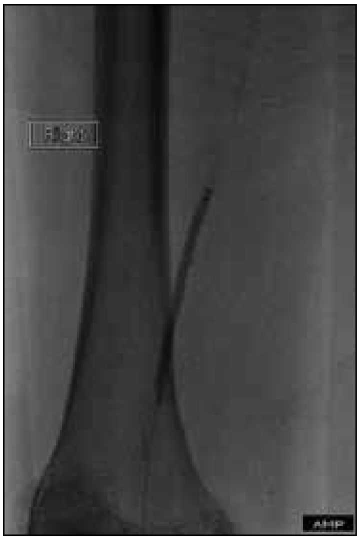

Figure 11. Balloon angioplasty after orbital atherectomy of the SFA.

Figure 12. Balloon angioplasty after orbital atherectomy of the popliteal artery.

Figure 13. Orbital atherectomy balloon angioplasty results in the SFA.

Step 8: Angiographic Assessment

A key concern after treating a lesion is determining the result of intervention. Ideally, the operator maintains wire access, with a 0.014-inch wire kept inside the vessel. A 0.018- or 0.035-inch catheter can be advanced over the wire. The Copilot system (Abbott Vascular, Santa Clara, CA) can be used to inject through the catheter and around the wire. The evaluation of angiographic results is performed in a stepwise fashion from supratibial to infratibial vessels (Figures 13 and 14). In the case described, the final angiogram injection was administered through the tibial sheath (Figure 15); maintaining wire access allows adequate visualization of the accessed tibial vessel. Visualization of the vessel beyond the access point is usually suboptimal, which is in part related to vessel spasm. If needed, the operator may choose to utilize the dilator of the microsheath (Terumo Interventional Systems) for injection after nitroglycerine injection. Visualization of the tibial vessels beyond the access point using this strategy usually allows for better assessment.

Step 9: Hemostasis

At the end of the procedure, ACT was obtained, and the sheath was removed immediately. For this patient, manual compression was used. After 10 minutes, no evidence of bleeding was visualized, and manual compression was stopped. The site was checked for bleeding and Doppler pulse every 15 minutes for a minimum of 1 hour. In the past, our practice has tried many of the hemostasis devices used for radial access, without adequate success.

We have found that after a TAMI procedure, patients may ambulate safely 30 minutes after hemostasis is achieved. This patient was discharged the same day.

PATIENT FOLLOW-UP

At time of intervention, this patient was receiving multidisciplinary care from a podiatrist, a wound care specialist, and an infectious disease specialist. She had been treated with sulfamethoxazole/trimethoprim, offloading, and silver alginate. After the procedure, the patient was found to be noncompliant with her antibiotic therapy and wound program. She developed sepsis and was hospitalized for 3 weeks.

First ray resection was performed, and treatment with vancomycin and sulfamethoxazole/trimethoprim initiated. The patient recovered and was discharged home with weekly wound clinic visits. She received debridement and negative-pressure wound therapy, as well as continued offloading (Figure 16).

Two months postprocedure (Figure 17), the patient was evaluated and found to have bleeding at the wound site, which is a positive predictor for wound healing potential. At 3 months postprocedure, wound healing was progressing with evidence of granulation, which is a strong indicator of vessel patency. Negative-pressure wound therapy was stopped, and mepilex border foam was initiated at this time.

Six weeks later, the patient was discharged from the wound clinic with a healed wound. The patient was seen in follow-up 5 months postprocedure with a fully healed wound and resolved rest pain (Figure 18).

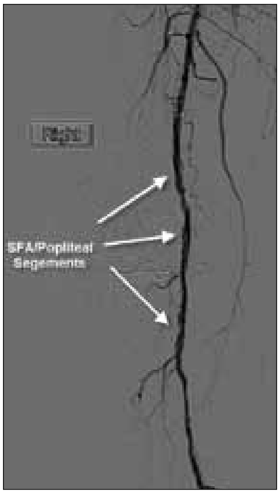

Figure 14. Orbital atherectomy balloon angioplasty results in the popliteal artery.

Figure 15. Final angiographic results in the posterior tibial artery with an injection through the side arm of the sheath.

Figure 16. Wound after initiation of negative-pressure wound therapy.

DISCUSSION

The exact prevalence of ulcers affecting the lower extremity is hard to estimate. In some reports, the percentage has been estimated at 1% to 2%.[6] This number is expected to rise in the US and other Western countries due to increased lifespans, the increased prevalence of PVD, and the increase in obesity and DM.

The elderly population is particularly significant; by the year 2030, they will constitute 19.3% of the US population.[7] The greatest number of ulcers occur in the elderly, both because of the increased incidence of atherosclerosis and the parallel increase in venous stasis disease.

DM is another epidemic that has an impact on our society, affecting patients of all ages. There are more than 25.8 million people in the US living with DM and its consequences.[8] Most patients presenting with lower-extremity ulcers have associated diabetes. The disease affects multiple aspects of PVD, starting with the diffuse atherosclerotic process and ending with the impact on wound healing and tissue oxygenation. This highlights the importance of a multidisciplinary approach to treating these patients.

Endovascular revascularization of patients with PVD has evolved dramatically. Our understanding of the atherosclerotic process has improved, and technological advancements have increased our treatment capabilities. Treatment modalities range from balloon angioplasty to stenting and atherectomy. New modalities of therapy include bioabsorbable stents and drug-eluting balloons.

Figure 17. Wound healing progression at 2 months postprocedure.

Figure 18. Fully healed wound at 5 months postprocedure.

The delivery of therapy has traditionally been through major arterial conduits, including the common femoral, brachial, or radial arteries. Arterial access may be challenging, depending on the patient's body habitus and other comorbidities. As technology improves, the crossing profile of our peripheral vascular devices is becoming smaller. The combination of sicker patients requiring revascularization treatment and the lower profile of peripheral vascular devices resulted in our implementation of the TAMI technique.

CONCLUSION

The TAMI technique is a novel approach to treat patients with advanced PVD and critical limb ischemia. We believe it is a natural evolution to begin utilizing tibiopedal access. As technology evolves and lower-profile devices continue to be developed, tibiopedal-based access and interventions will see increased use. However, a study of a larger series of patients to document efficacy and safety is needed to further evaluate these interventions. More will be learned about appropriate patient selection as physicians continue to apply the technique in complex subsets of patients. ■

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1. Tsai AW, Folsom AR, Rosamond WD, Jones DW. Ankle-brachial index and 7-year ischemic stroke incidence: the ARIC study. Stroke. 2001;32:1721-1724.
2. Newman AB, Shemanski L, Manolio TA, et al. Ankle-arm index as a predictor of cardiovascular disease and mortality in the Cardiovascular Health Study. The Cardiovascular Health Study Group. Arterioscler Thromb Vasc Biol. 1999;19:538-545.
3. Meijer WT, Hoes AW, Rutgers D, et al. Peripheral arterial disease in the elderly: the Rotterdam study. Arterioscler Thromb Vasc Biol. 1998;18:185-192.
4. McDermott MM, Greenland P, Liu K, et al. The ankle brachial index is associated with leg function and physical activity: the Walking and Leg Circulation Study. Ann Intern Med. 2002;136:873-883.
5. Hirsch AT, Criqui MH, Treat-Jacobson D, et al. Peripheral arterial disease detection, awareness, and treatment in primary care. JAMA. 2001;286:1317-1324.
6. London NJ, Donnelly R. ABC of arterial and venous disease. Ulcerated lower limb. BMJ. 2000;320:1589-1591.
7. A Profile of Older Americans: 2011. Washington, DC: US Dept of Health and Human Services Administration on Aging; 2011.
8. National Diabetes Statistics Fact Sheet: General Information and National Estimates on Diabetes in the United States, 2011. Washington, DC: US Dept of Health and Human Services National Diabetes Information Clearinghouse; 2011.