TAMI: A New Technique in Critical Limb Ischemia Revascularization

A novel use of the Boston Scientific TruePath™ CTO Device in the treatment of advanced peripheral vascular disease.

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The number of patients living with peripheral vascular disease (PVD) in the United States will continue to increase and will exceed 20 million by the year 2030.[1-5] But this epidemic is not isolated to Western countries. A recent analysis evaluating the prevalence of PVD in third-world countries shows an increase of 27%.[6] The overall incidence of critical limb ischemia (CLI) and lower extremity arterial ulcers has been estimated at 1% to 2%.[7]

Endovascular revascularization of patients with PVD has evolved dramatically, and we now have a better understanding of the atherosclerotic process. Traditionally, therapy has been delivered through major arterial conduits, such as the common femoral artery (CFA), brachial artery, or even radial arteries. Arterial access may be challenging, depending on the patient's body habitus and any comorbidities, although a positive step forward by our industry partners is the fact that the crossing profiles of our peripheral vascular devices are becoming smaller. Tibiopedal arterial minimally invasive retrograde revascularization (TAMI technique) is a revascularization modality by which the operator obtains tibiopedal access and revascularizes the lower extremity via tibial access only.

The TruePath™ CTO Device (Boston Scientific Corporation, Natick, MA) was designed to penetrate hard or calcified occlusions with a diamond-coated tip that rotates at 13,000 rpm. This unique feature has gained significant interest in treating severely calcified CTOs, especially in patients with CLI who tend to have unusually high levels of dense calcium deposits in their CTO caps. In our practice, we have seen this device penetrate a dense calcific CTO cap under ultrasound. We believe the risk of perforations would be less in these dense, calcified lesions.

Our experience has led us to conclude that not all crossing tools are created equal, and each has a place in an algorithmic approach to crossing complex CTOs. The TruePath device offers a unique advantage in dealing with bulky, calcified CTO caps, which tend to deflect away many crossing tools as once the CTO is penetrated, the body of the device can advance into the true lumen. The rotating tip will drill through the cap, engaging the device within the lesion, thus decreasing the chance of perforation or becoming immediately subintimal.

One highly differentiated feature of this device is its low, 0.017-inch profile, which allows it to be used via tibial retrograde access in sheaths as small as 2.9 F via an 0.018-inch support catheter, such as the Rubicon™ Support Catheter (Boston Scientific Corporation). This low-profile combination delivers robust energy to tackle complex CTOs from the retrograde approach.

We typically prefer to use the device with an angled, 0.018-inch support catheter, such as the CXI support catheter (Cook Medical, Bloomington, IN). This allows the operator to more easily direct the TruePath device where needed and deliver it to the target lesion. By rotating the 0.018-inch support catheter, the operator can obtain 360° access to the target. The simple maneuver of combining an angled catheter with a straight TruePath device adds significant value and enables a higher success rate for calcified CTO caps. If this combination does not work, the operator may choose to bend the TruePath tip for added steerability. A prepackaged shaping tool is included with the device, which allows the operator to impart a 15° angle to the tip.

In patients with severe disease before the lesion location, the operator may choose a 0.035-inch support catheter passed through a 4-F Precision sheath (Terumo Interventional Systems, Somerset, NJ). We typically utilize the NaviCross catheter (Terumo Interventional Systems) to direct the TruePath device. The device is then activated and advanced across the lesion. The working length is 165 cm, which can be extended up to 335 cm with the addition of a wire extension to allow for support catheter or balloon catheter exchanges. In cases where the TAMI technique is used, the operator will advance the support catheter to the true lumen. Once adequate blood return is confirmed, a contrast injection will confirm the position. At this point, the operator may choose the modality of therapy.

CASE PRESENTATION

A 72-year-old woman with a medical history significant for coronary artery disease, diabetes, hypertension, and chronic kidney disease developed an ulcer involving the plantar and dorsal aspect of the right great toe. The distribution of the ulcer corresponded to both the anterior and posterior tibial arteries. The ulcer placed the patient at Rutherford class V. There were two attempts to revascularize the right lower extremity through a traditional left CFA retrograde approach and a right antegrade approach. Both attempts were unsuccessful, and the patient was recommended for a major above-the-knee amputation. Because of the heavy calcification and severity of the disease, revascularization via the TAMI technique was chosen.

The TAMI Technique

When the operator chooses the TAMI technique, the distal cap is usually engaged first. The TruePath device is extended 1 cm beyond the tip of the support catheter (Figure 1). The TruePath device is activated and slowly advanced. It is important that the operator does not put too much pressure on the device, as it is advanced to allow the drill to engage the lesion. Attempting to push, prolapse, or torque the device through the lesion works against the drilling mechanism. Applying significant pressure may advance the drill into a subintimal space or, in some cases, perforate the vessel. As the device is advanced through the lesion, the support catheter should be advanced to maintain the consistent 1-cm distance between the support catheter and the tip of the TruePath device. As with standard CTO wire techniques, the device will often cross more effectively by advancing both the TruePath™ and the support catheter as a system.

CTOs are complex and may require multiple catheter and wire exchanges. It has been our experience that penetrating the distal CTO cap is easier than penetrating the proximal cap.

CTOs are one of the last unconquered territories in the peripheral space, and crossing techniques continue to benefit from the advancement of many new devices, including the TruePath device.

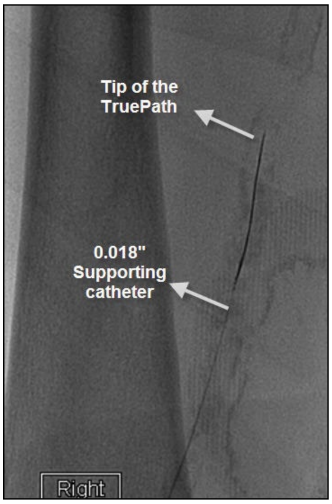

Figure 1. The TruePath™ tip engaging the distal CTO cap via the 0.018-inch catheter from retrograde access.

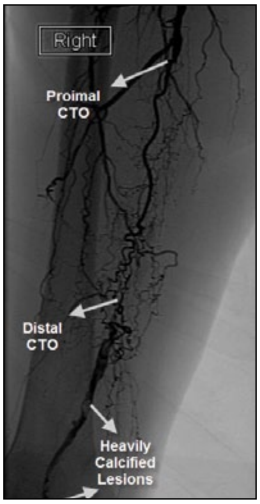

Figure 2. Diagnostic angiogram showing the proximal and distal CTO caps.

TruePath™ Operator Feedback

The TruePath device has audible signals that indicate the amount of resistance at the drill tip. The first two green lights signify whether the device is in active and drilling mode, respectively. When the resistance exceeds specifications, the third light, which is red, will illuminate, and the device will emit a "chirp." In this mode, the tip oscillates to relieve pressure on the drive shaft. When the device enters this mode, the operator must determine what is causing the increase in resistance. Pushing too hard on the device as it advances can trigger this mode. Often, easing the forward pressure will allow the device to return to drill mode as the operator engages and advances in the lesion.

The tip overload mode can also be encountered while traversing the lesion. This mode can provide important feedback as to whether the device is taking a subintimal track, and it can allow the operator to redirect the catheter and device to stay in the true lumen. Upon hearing this feedback, the operator can take additional views and use calcium outlines to determine device position. We typically employ an angled support catheter to direct TruePath in case of tortuosity. The operator may choose an 0.018-inch or 0.035-inch support catheter, depending on the pedal sheath that is used.

STEPWISE TAMI PROCEDURE DESCRIPTION

A key to improving the chances for successful revascularization using the TAMI technique is having a detailed angiographic evaluation. This includes selective angiography of the limb that is being treated. Selective angiography will uncover vascular conduits that were

Figure 3. Patient position on the catheterization table with tibial access for the TAMI procedure.

Figure 4. Operator and ultrasound technician position in relation to the patient.

thought of as nonexistent before. In our experience, the CTO segment is usually shorter than what originally was thought. In the current case, the patient was already recommended for amputation, and two attempts at revascularization failed prior to the current procedure. The patient underwent diagnostic angiography that showed a long CTO with severe calcification (Figure 2).

Step 1: Patient Placement. The patient was placed on the catheterization table in reverse fashion, with the head of the patient to the right of the operator to allow for antegrade and retrograde access (Figures 3 and 4).

Step 2: Access. With the presence of a vascular technologist, the tibial artery required for access is studied under ultrasound (US). We typically employ a hockey-stick–shaped probe. This probe employs a variable frequency between 7 and 15 MHz. Depending on the tibial vessel required for access, the leg is positioned accordingly. The operator is looking for the needle and aiming toward the tibial vessel. Identifying the tibial veins is very important, in order to avoid any venous sticks. A venous stick might predispose to access site complications, such as arteriovenous fistulas.

Step 3: Successful Arterial Cannulation. The needle trajectory is monitored under US guidance. After vessel puncture, the operator should observe the bright blood return. Pulsatile blood flow is never present.

Step 4: Access Wire Introduction. After introducing the access wire, a microsheath is introduced. The wire is introduced through the needle. The US technician will switch orientation from cross-sectional to longitudinal. At our institution, we use the Terumo Precision Microsheath and the Cook tibiopedal microsheaths (Cook Medical). The access wires have an atraumatic tip. The body of the wire is supportive and will allow the introduction of the sheath. The sheath is introduced, and depending on the anatomy of the patient, the tip of the sheath may be visualized under US, or a retrograde angiogram through the sheath may be obtained.

Step 5: Intra-arterial Medication. Once the sheath is secured inside the artery, full weight-based anticoagulation with heparin will be given (60–80 U/kg). Injecting heparin will create a burning sensation. Depending on the patient's blood pressure, 300 to 400 µg of nitroglycerin can be injected through the side arm of the sheath. Nitroglycerin may be injected at 5- to 10-minute intervals. Activated clotting time (ACT) is checked at 20-minute intervals. The ideal ACT target during these procedures is maintained between 200 and 250 seconds. Another option for treating the vessel with nitroglycerin every 5 to 10 minutes is using the TAMI solution (Table 1). Instead of frequent injections, the solution can be infused intra-arterially at a rate of 6 to 7 mL/min. The continuous infusion will decrease the chance of vasospasm and arterial thrombosis.

Step 6: CTO Crossing and Revascularization Strategy. Choosing the modality of therapy depends on the lesion being treated. The TruePath device requires a support catheter to help deliver the energy to the CTO cap (Figure 1). In our experience, working via a CXI 0.018-inch angled catheter (Cook Medical) or a NaviCross 0.035-inch angled catheter allows us to direct the tip of the TruePath without damaging the device or losing the ability to engage the CTO cap. After crossing the CTO cap, the support catheter must follow the tip. Once the CTO is crossed, an angiogram through the support catheter can confirm our position within the true lumen. In this example, after crossing, we choose to perform orbital atherectomy followed by balloon angioplasty (Figures 5 and 6). Final angiographic assessment should be performed via pedal access through the support catheter. The angiogram should include the tibial access site (Figures 7 and 8).

Figure 5. Orbital atherectomy of the popliteal and superficial femoral arteries.

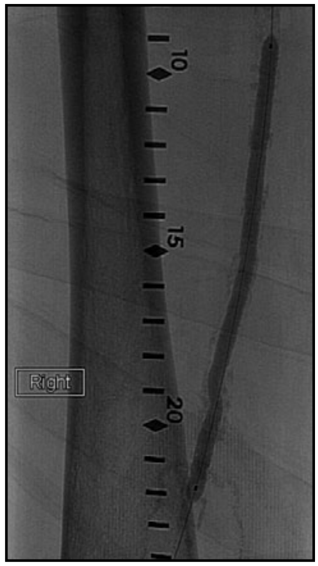

Figure 6. Balloon angioplasty of the SFA and popliteal arteries.

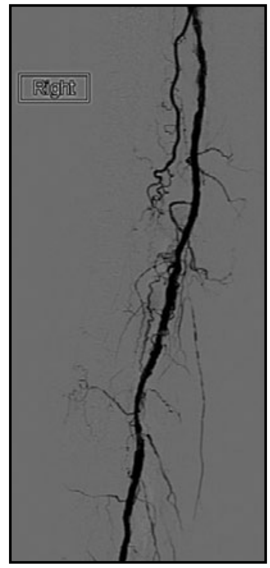

Figure 7. Final angiogram of the CTO segment of the SFA/popliteal arteries.

Figure 8. Final angiogram of the posterior tibial artery into the plantar vessels via tibial access.

Step 7: Hemostasis. At the end of the procedure, the sheath will be removed immediately. It is our practice to document an ACT before sheath removal. Currently, we are using the same hemostasis devices that are applied for radial access. One unique device is the Boa device (Lakeshore Medical Innovations, Byron Center, MI), which is basically a band with two parallel ridges that achieve hemostasis at the access site. The site is checked every 15 minutes. Once there is no visible bleeding, the hemostasis device is removed. Our patients will ambulate 30 minutes after hemostasis is achieved.

Our patient started with a monophasic posterior tibial pulse and ended with a palpable posterior tibial pulse. Eventually, the patient required toe amputation, and the limb was preserved.

DISCUSSION

Accessing major vascular conduits through the groin area has long been the traditional means of delivering therapy. The relationship between bony landmarks and the CFA is well established. Retrospective studies showed the benefit of fluoroscopy when trying to access the CFA.[8-13] Anatomical variation with the CFA bifurcation is well documented. High bifurcation of the superficial femoral artery (SFA) and profunda has been documented in up to 35% of patients.[14] US guidance has been shown to be an effective tool in difficult access cases.[9] The use of US guidance has been particularly effective in facilitating vascular access, including femoral and tibial access in patients with CLI.[15]

In the past, the complexity of tibial vessel anatomy and disease in CLI patients prohibited operators from revascularization, but this is no longer the case, as clinicians understand the implications of amputation and the impact on patient morbidity and mortality. Mortality rates range anywhere from 40% at 2 years up to 70% by 5 years.[16] Treating tibial vessels in CLI patients is one of the mainstays of limb salvage.

The use of ultrasound, fluoroscopy, and Doppler strategies offers a great advantage in cannulating the CFA. Despite the improvement in technical skills and access strategies, the use of lower-profile devices, and the judicious use of anticoagulation, complications still occur. These complications include hematomas, arteriovenous fistulas, pseudoaneurysm, nerve compression, and retroperitoneal bleed, to name a few. There are multiple risk factors that will increase the risk of these complications. Age, large sheath size, antiplatelet therapy, obesity, and above all, PVD are common risk factors in our patients.[17-19] Groin complications causing bleeding or requiring blood transfusion are not a benign phenomenon; these are associated with significant morbidity and mortality.[20-25]

The idea of delivering therapy in high-risk CLI patients while decreasing the risk of access complication, bleeding, and transfusion is both challenging and compelling. A recent analysis examined the safety and feasibility of the TAMI approach, comparing a TAMI technique cohort to a traditional-access cohort.[26]

TABLE 1. TAMI SOLUTION COMPOSITION
500 mL heparinized normal saline
3,000 µg nitroglycerin
2.5–5 mg verapamil

Overall, the TAMI cohort patients had more comorbidities and a higher Rutherford class. Tibial vessels were clearly more fragile and of smaller caliber. The ability to use a CTO crossing device through a low-profile sheath is important in these cases. TruePath can be delivered through a 0.018-inch catheter, so the operator can capitalize on the unique features of the device without increasing sheath size, and subsequently, rates of complication.

The TAMI technique is unique in allowing the operator to access, cross, and treat patients with advanced peripheral vascular disease. With new technologies, such as the TruePath device, more and more patients may receive revascularization via tibial access. Despite the multiple comorbidities affecting these patients, a standardized approach was shown to be safe and effective. The TAMI approach should not be attempted in any patient without adequate lumen visualization allowing for tibial vessel cannulation.

The TAMI technique offers some advantages, such as a potential decrease in the rate of bleeding and the need for transfusions. Decreasing the rate of groin complications in cardiac patients undergoing angioplasty through a radial approach has also been correlated with a lower morbidity and mortality.[27]

CONCLUSION

The TAMI technique is a novel approach to treating patients with advanced PVD and CLI. New technologies facilitating crossing of CTOs, such as the TruePath™ CTO Device, will allow more complex disease to be addressed without increasing the risk of complications. The TruePath Device is easy to use, with multiple built-in safety features and a low crossing profile. The TAMI technique is feasible because of the low crossing profile of newer endovascular devices. Use of the technique offers tremendous potential: improved patient safety, reduced contrast usage, and reduced radiation exposure to both the patient and operator. We believe that this approach, when chosen in the right subset of patients, will have a positive impact on patient outcomes. ■

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Results from case studies are not necessarily predicative of results in other cases. Results in other cases may vary.

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