

A New Approach to Diagnosing and Treating CLI

This classification and intervention scoring system was created to provide precise treatment to the target vessel and optimize outcomes.

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Unfortunately, amputation without arterial angiography continues to be an acceptable practice around the globe for the treatment of critical limb ischemia (CLI). Historically, this practice was accepted because although angiography could lead to identification of severe tibiopedal occlusive arterial disease, we had no known treatment alternative to offer the patient. With the advent of new technology coupled with the skills of experienced interventional operators, this practice should no longer be acceptable. It is critical to perform arterial angiography on all patients presenting with lower extremity tissue loss and/or gangrene for accurate diagnosis of severe tibiopedal occlusive arterial disease. This article describes the mechanism to accurately diagnose and intervene on complex tibiopedal occlusive arterial disease.



Figure 1. Grade 0 Jenali tibial runoff. No tibial vessel runoff to the foot. No collateral mediated tibial vessels reconstitutions, consistent with Jenali collateral scoring system level 3.

CLASSIFICATION AND INTERVENTION PROTOCOL

The three tibial vessels are the anterior tibial artery located laterally, the peroneal artery located centrally, and the posterior tibial artery located medially.

To make a clinical decision on how to intervene, Dr. Mustapha has developed the Jenali Tibial Runoff Classification and Intervention Protocol to provide precise therapy to the target vessel supplying blood to the area with tissue loss and gangrene for optimum outcomes after peripheral vascular intervention (PVI) (Table 1).

Dr. Mustapha developed the Jenali Collateral Scoring System to define the severity of ischemic disease in the

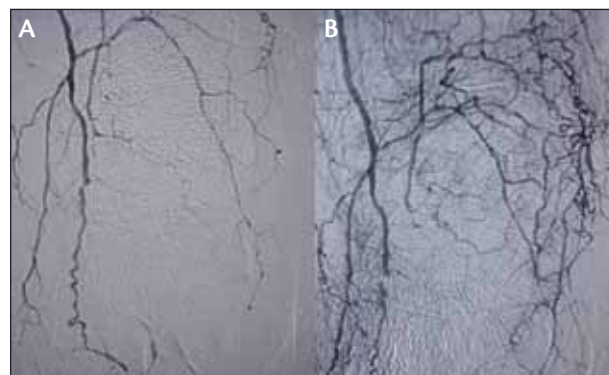


Figure 2. Tibiopedal runoff at 9 seconds, Jenali collateral scoring system level 3 (A). Tibiopedal runoff after intra-arterial nitroglycerine 400 mcg and advancement of the diagnostic catheter to selective midpopliteal versus distal external iliac artery (B) as in Figure 2A.

TABLE 1. JENALI TIBIAL RUNOFF CLASSIFICATION AND INTERVENTION PROTOCOL

Classification	Intervention Protocol
Grade 0: No straight-vessel runoff (Figure 1)	a. First, treat the vessel with the shortest CTO lesion.
	b. If there is retrograde flow back to the anterior communicating artery (ACA), then no further intervention is needed at this time. Foot revascularization is considered complete with a high likelihood for ulcer to heal.
	c. If there is no retrograde flow back to the ACA, then further tibial intervention is indicated. Consider treating the vessel that supplies the target lesion in an attempt to obtain retrograde flow to the ACA via the pedal arch.
	d. Complete foot revascularization with retrograde flow to the ACA is optimal.
	e. Re-evaluate tibiopedal runoff after intervention.
Grade 1: Single-vessel runoff	a. Single-vessel runoff to the foot with normal retrograde flow back to the ACA with no tissue loss or gangrene, no endovascular therapy indicated.
	b. Approach single-vessel runoff with the presence of tissue loss or gangrene by mapping the tibial vessel that supplies the target area of tissue loss or gangrene and intervene on that vessel to provide direct flow into the ischemic area.
	c. All single-vessel runoff with $\geq 70\%$ stenosis and Rutherford Becker classification 4 requires endovascular aggressive treatment.
Grade 2: Two-vessel runoff	a. If normal antegrade flow to the foot is present, no intervention is indicated.
	b. If one vessel with $\geq 70\%$ stenosis and is not filling distally from a patent tibial vessel, intervention is indicated.
	c. If one vessel with $\geq 70\%$ stenosis and is filling distally from a patent tibial vessel, no intervention is indicated.
	d. If both vessels have $\geq 70\%$ stenosis, intervention is indicated for both vessels.
Grade 3: Three-vessel runoff	a. If normal antegrade flow to the foot is present, no intervention is indicated.
	b. If two vessels with $< 70\%$ stenosis and one with $\geq 70\%$ stenosis and tissue loss or gangrene is present in the distribution of the occluded vessel, opening of the $\geq 70\%$ stenotic vessel is indicated.
	c. If no tissue loss or gangrene is present, no intervention is indicated.

setting of absent straight tibial runoff to the foot (Table 2). The level increases in direct proportion to the severity of ischemia. A high level of ischemia indicates an urgent need to recanalize the target tibial vessel for limb preservation.

TIBIAL COLLATERALS

Understanding the value of tibial collaterals is crucial in diagnosing and treating CLI. Collaterals are formed as a de novo bypass to a diseased vessel that transitions from high-grade stenosis to total occlusion. The mechanism of neogenesis of the collateral system has been described in the literature for many years. However, tibial collaterals have not been defined in the literature as an entity but rather described vaguely with minimal significance. When considering the value tibial collaterals

provide to the lower extremities, a detailed evaluation of both their distribution significance and structural connections is critical to the recanalization of totally occluded vessels. Also, collaterals play an important role in mapping flow distribution in patients with tissue loss or gangrene.

With our aging population living well into their 80s with comorbid conditions contributing to tibiopedal disease, it is not surprising we are noticing a steady rise in lower limb amputations due to peripheral arterial disease (PAD).¹ In general, without tibial collaterals, peripheral vascular disease would claim a significantly higher number of limbs due to amputation.

As described, neogenesis triggers new vascular growth mostly originating at the site of the proximal chronic total occlusion (CTO) cap and reconstitutes

TABLE 2. JENALI COLLATERAL SCORING SYSTEM

Level 3: No tibial vessel reconstitution at 9 seconds after contrast injection (Figure 2).
Level 2: Delayed tibial vessel reconstitution at 6 seconds after contrast injection (Figure 3).
Level 1: Delayed tibial vessel reconstitution 3 to 5 seconds after contrast injection (Figure 4).
Level 0: Immediate tibial vessel reconstitution after contrast injection (Figure 5).

slightly distal to the distal CTO cap. This leaves a segment of hibernating vessel between the proximal and distal caps, hence the phenomenon of hibernating lumen vessels (Figure 6). A hibernating lumen is a vessel collapsed secondary to inflow and outflow obstruction by proximal and distal caps.

CHRONIC TOTAL OCCLUSIONS

Historically, CTOs have been met with varied approaches and inconsistent results. The development of subintimal recanalization led to a revolutionary approach to treatment of above-the-knee CTO vessels. This ingenious approach helped thousands of patients. However, this approach leads to unnecessary stenting of long segments in otherwise patent vessels because it does not allow identification of hibernating lumens.

As technologies continue to improve, new devices are being developed to more precisely traverse the CTO caps both proximally and distally, which lends to intraluminal recanalization and saves long segments of vessels from being unnecessarily stented. With the aid of the new crossing devices, intraluminal CTO crossing is much safer and quicker than the subintimal recanaliza-

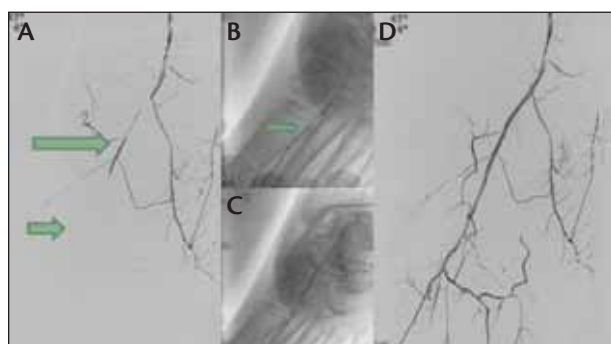


Figure 3. Unique combination between Jenali collateral scoring level 3 (short arrow) and Jenali collateral scoring level 2 (long arrow) (A). PTA of the distal dorsalis pedis into the great toe's proximal branch (B). Dorsalis pedis during PTA (C). Postintervention hibernating pedal vessels and patent anterior pedal arch (D).

TABLE 3. JENALI ZONES IDENTIFICATION

Zone 1 defines the proximal third of the tibial runoff distal to the popliteal artery.
Zone 2 defines the mid-third of the tibial runoff above the ankle joint.
Zone 3 defines the distal third of the tibial runoff below the ankle joint.

tion technique. Theoretically, crossing of long CTO segments via an intraluminal approach can transform a long lesion into a short single segment (or at most two short segments) at the site of the proximal and distal caps leaving the area of hibernating lumen without intervention (Figure 7). Based on the data published, the long-term patency of short treated segments versus long treated segments lend to longer patency.²

The current CTO devices allow operators to maintain intraluminal presence, which allows intervention on short segments of a long CTO vessel secondary to discovery of the hibernating lumen that otherwise would have been lost had the recanalization had been via a subintimal approach.

ZONING AND MAPPING

Zoning allows the operator to precisely describe the diseased vessel segment and its location below the knee in a CLI patient. The authors describe Dr. Mustapha's method of zoning in Table 3.

It is important to describe each tibial vessel individually to assist with mapping, especially in the presence of tissue loss or gangrene. This allows a full description of the vessel's distribution and understanding of its contribution to the supplying area. Hence, the use of tibial staging combined with collateral staging and tibial zoning can describe the tibial arteries with precise definition.

Single-vessel runoff is a phenomenon that is somewhat accepted as significant blood supply to the foot. Currently, many patients with one- and two-vessel



Figure 4. A 54-year-old man with a nonhealing infected wound (A). Dehiscent wound site (B).



Figure 5. Jenali collateral scoring system level 0. Indicates immediate tibial vessel reconstitution after contrast injection.

runoff still present with nonhealing ulcers (Figures 8 and 9). Therefore, a mapping technique that defines the exact skin area that is affected by insufficient blood supply is a valuable diagnostic step in identifying the true culprit tibial vessel that requires the most urgent revascularization (Figures 10 and 11). Mapping has been well described by the angiosome method.³

Tibial access is crucial in limb salvage procedures (Figure 12). It expedites the reconstitution of the target vessel by accessing the vessel that has been identified by angiosome mapping. Operators revascularize the exact vessel that is required for optimal healing for the area with tissue loss or gangrene. One or two-vessel runoff is the goal for best patient outcomes as long as all segments of the foot are well vascularized.

Six angiosomes of the foot and ankle are supplied by the three main tibial arteries: the anterior tibial



Figure 6. Arterial mapping in patient with CLI (A). Hibernating AT and dorsalis pedis arteries (B). Hibernating dorsalis pedis and pedal arch (C). Skin mapping in a patient with dry gangrene involving the first and second toes (D, E). Preintervention arterial and skin mapping. Arterial mapping with no reconstitutive flow to the pedal arteries after 9 seconds (Jenali collateral scoring system level 3) (F). Skin mapping showing ischemic changes involving all tibiopedal arterial distribution as shown in Figure 7F (G). Postintervention arterial and skin mapping (H, I). Note the hibernating pedal vessels that were not present during the preintervention arterial mapping (I).

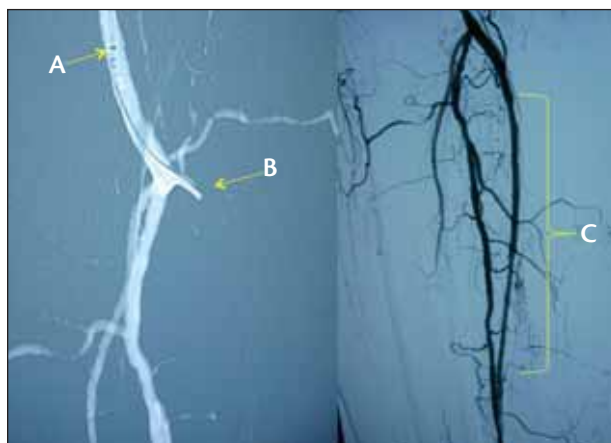


Figure 7. CTO crossing device (A). Guidewire at the CTO cap in the AT (B). Anterior tibial (AT) after recanalization with hibernating lumen (C).

artery (ATA), the posterior tibial artery (PTA), and the peroneal artery (PA). The ATA becomes the dorsalis pedis artery, which supplies the dorsum of the foot. The PA has two branches that supply the lateral border of the ankle and the outside of the heel.

The anterior perforator supplies the anterolateral part of the ankle. The calcaneal supplies the plantar aspect of the heel. The PTA supplies the plantar aspect of the toes, the web spaces between the toes, the sole of the foot, and the inside of the heel.

The PTA has three major branches that supply distinct portions of the sole of the foot:

- The calcaneal branch → heel
- The medial plantar → instep
- The lateral plantar → lateral midfoot and the forefoot

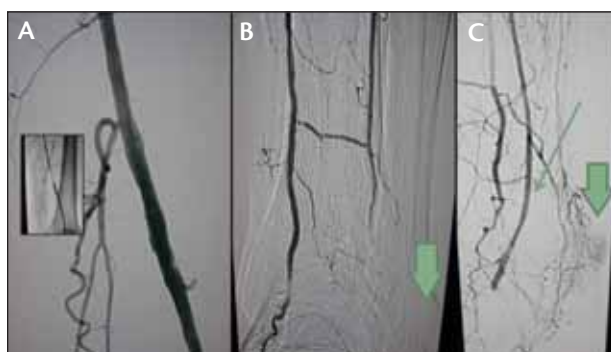


Figure 9. Final angiogram after endovascular intervention on the left popliteal and the left anterior tibial arteries. Pre-(insert) and postpopliteal intervention (A). Large arrow showing preintervention ischemic tissue loss region (B). Large arrow showing postintervention hyperemic flow to the tissue loss region (C). The newly opened anterior tibial artery and total occlusion of the dorsalis pedis (small green arrow).

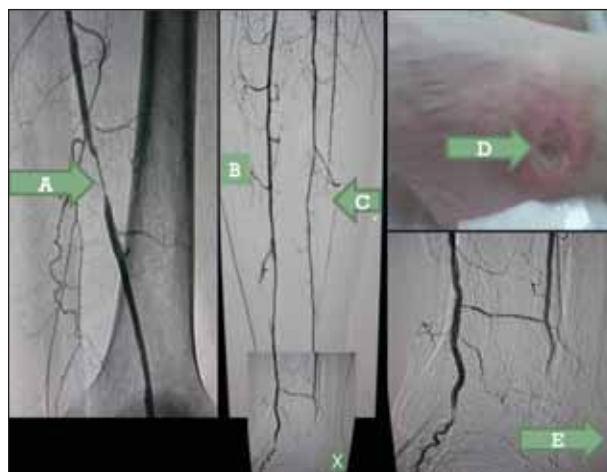


Figure 8. Patient with two-vessel runoff and 4-month-old nonhealing ulcer. Based on the initial evaluation from a catheter placed in the left common iliac artery, it was believed that the popliteal lesion was the cause of the non-healing ulcer. After selective angiography of the tibial vessels and proper mapping, the anterior tibial artery was found to be the culprit vessel. Popliteal lesion (A). Two-vessel runoff without any direct blood flow to the ulcer region indicated by X (B). Anterior tibial total occlusion (C). Skin mapping and nonhealing ulcer (D). Arterial mapping showing significant ischemic tissue loss (E).

Overall, acquiring direct flow based on the angiosome concept is important for limb salvage by endovascular therapy in patients with CLI.



Figure 10. Skin mapping in ischemic foot with tissue loss and gangrene. Dry gangrene skin changes involving the heel (A). A unique location with dual arterial blood supply: (1) the calcaneal branch of the posterior tibial (PT) artery and (2) the calcaneal branch of the peroneal artery. Dry gangrene changes on the proximal dorsum of the foot, mainly supplied by the anterior tibial artery (B). Purplish great toe skin changes and skin breakdown, consistent with AT occlusion (insert). The skin mapping in the patient indicated all tibial arteries are occluded.

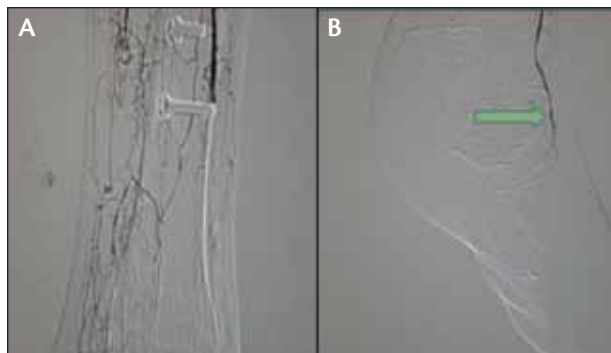


Figure 11. Arterial angiogram mapping to compare with the skin mapping in Figure 10. As predicted by the skin mapping, all tibial arteries are totally occluded (A). Faint reconstitution of the dorsalis pedis artery (arrow) with Jenali collateral scoring of 1 (B).

BTK/BTA CTO CROSSING APPROACH

The priority for the below-the-knee (BTK) and below-the-ankle (BTA) CTO crossing approach is to stay intraluminal. Many of the CTO vessels have long segments of hibernating lumens that do not require additional intervention after inflow and outflow have been opened via percutaneous intervention. However, once the interventional devices penetrate the subintimal space, we lose this major opportunity for intraluminal recanalization.

Unfortunately, there currently are no optimal long stents or subintimal balloon angioplasty devices available that provide long-term patency. There are no strong data to support subintimal recanalization in the tibiopedal vessels.

In tibial CTOs, the most common origin and reconstitution is the proximal and distal portion of the tibial vessel (Jenali zones 1 and 3). These lesions are known to be heavily calcified. Dr. Mustapha's experience with intravascular ultrasound (IVUS) after percutaneous transluminal angioplasty shows a higher incidence of dissection and larger calcified lesions than without IVUS. Dr. Mustapha also finds tibial vessels in Jenali zone 3 to average 2.5 mm and increase up to 4 mm in Jenali zone 1.

In Dr. Mustapha's experience, the majority of pedal vessels are hibernating and tend to plump up nicely, with great blush as well, once reached intraluminally. BTA vessels are delicate and tortuous, yet their patency is crucial for successful limb salvage in CLI patients. BTA CTO lesions are usually short (10–20 mm) and tolerate atherectomy, angioplasty, and stenting if necessary. The anterior arch is almost always patent.

Aggressive medical therapy for risk-factor modification that includes dual-antiplatelet therapy as tolerat-

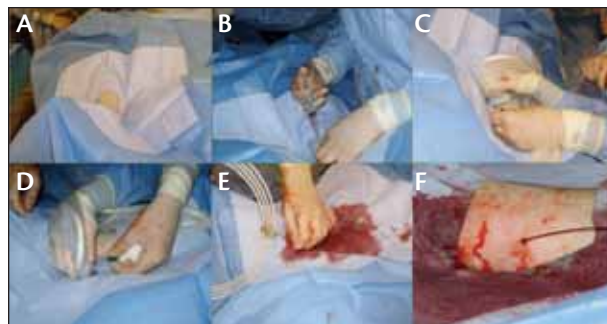


Figure 12. Tibial access in limb salvage procedure. Prepping the tibial access site (A). Applying local anesthetic (B). Ultrasound-guided micro kit needle access (C). Needle is parallel to the ultrasound beam and perpendicular to the artery (D). Interventional wire advanced through micro-sheath (E). A 0.018-inch catheter in the tibial artery (F).

ed along with lipid-lowering agents in conjunction with antihypertension medications, good diabetic control, low-fat/low-cholesterol diet, and a walking exercise program are important after intervention to decrease the rate of reocclusion of the native vessels due to atherosclerosis.

CONCLUSION

It is not the number of tibial vessel runoffs to the foot that ensures resolution of ischemia; it is the tibial vessel runoff to the foot that supplies an ischemic area that ensures resolution of ischemia. Utilizing the Jenali Tibial Runoff Classification and Intervention Protocol, the Jenali Collateral Scoring System, and Jenali Zones Identification provides the operator the ability to provide a precise, accurate diagnosis and successful treatment. ■

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