

WHAT WOULD YOU DO?

Critical Limb Ischemia and Gangrene

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PANEL: TONY S. DAS, MD, FACP, FACC; ROBERT A. LOOKSTEIN, MD; AND PETER A. SCHNEIDER, MD

CASE PRESENTATION

A 76-year-old woman with a history of hypertension, hyperlipidemia, and chronic myeloid leukemia treated with hydroxyurea presents for a second opinion regarding potential below-the-knee (BTK) amputation. There is no evidence of coronary artery disease. On a previous evaluation, she had rest pain her right lower limb consistent with a superficial femoral artery (SFA) obstruction, which was treated with a drug-eluting stent (DES); however, occlusion was noted within 1 year of the procedure. Secondary treatment included femoral BTK (peroneal) bypass with autologous vein, but the graft failed within 1 year. Now, the patient has gangrene on digits 2 and 3 and rest pain. Noninvasive evaluation shows a right ankle-brachial index (ABI) of 0.35 and a left ABI of 0.45. Duplex ultrasound reveals an occluded right SFA and bypass graft, occluded anterior and posterior tibial arteries, and the peroneal artery is patent with severe proximal disease.

Dr. Das: The patient is elderly and has multiple comorbidities and chronic lymphoma. She presents with resting pain and previous failed intervention (DES), which is a marker of a poor outcome. In addition, she failed femorotibial bypass with a vein, which again portends a poor outcome. I would proceed with angiography. In my opinion, there is no need to do CTA or MRA with resting pain and gangrene—digital subtraction angiography (DSA) will provide the most useful information.

Dr. Lookstein: I would perform a revision of the native circulation into the peroneal artery. In the setting of gangrene, I preferentially place stents, so I would probably use a DES after debulking the entire SFA and popliteal artery and ensure there is straight flow into the peroneal artery.

CASE CONTINUED

The patient is taken to the angiography suite and imaging is performed (Figures 1–7). The results of imaging corroborate the results of noninvasive testing, with occlusion of the SFA and infrapopliteal segments and occlusion of the bypass graft.

The interventional strategy is to proceed with contralateral access and a cross-over technique with recanalization of the right SFA chronic total occlusion (CTO) and treatment with a 5-mm In.Pact Admiral drug-coated balloon (DCB; Medtronic) in the proximal and distal segments of the SFA, as well as a 4-mm In.Pact Admiral DCB in the popliteal artery. Outflow is reestablished through the popliteal artery, and an attempt is made to treat the CTO in the anterior tibial artery, but it is not aggressively pursued.



What should be the course of therapy and management plans?

Dr. Schneider: I definitely would not consider BTK amputation. She has runoff, is not diabetic, and her lesions are limited to the toes. Based on the Wound, Ischemia, and foot Infection (WIFI) classification system, this patient has a wound grade 1 to 2, ischemia grade 3, and foot infection grade 0, which puts her at WIFI class 3 to 4 (high risk for limb loss without revascularization). The sooner revascularization is performed, the better, because the foot may not heal with peroneal revascularization alone if the damage worsens. If you get good revascularization of the peroneal artery, whether with an open or endovascular approach, I would perform early toe amputation.

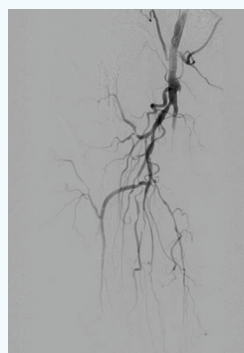


Figure 1. Right common femoral artery.



Figure 2. Mid-thigh arteries.

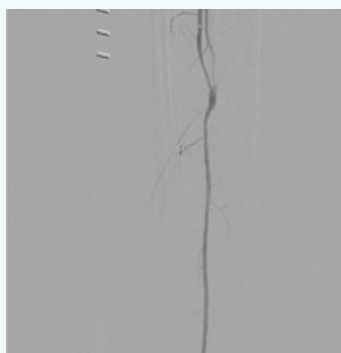


Figure 3. Joint space and infrapopliteal artery.

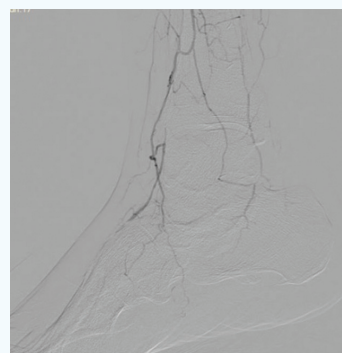


Figure 4. Vasculature of the foot.



What is your opinion regarding initial management plans and interventions?

Dr. Schneider: This patient has a decent peroneal artery and runoff to the foot with at least some identifiable pedal vessels. I am worried that the dorsalis pedis artery is badly diseased. Although this is likely the correct angiosome, it is not clear if revascularization will deliver adequate perfusion. The patient should be informed that she may lose the leg, even with patent reconstruction. Surgical options include bypass from the common femoral artery to the peroneal artery using the contralateral saphenous vein, arm vein, or CryoVein (CryoLife, Inc.). If the foot worsens, you would have to go to dorsalis pedis access. However, I would use open surgery as my backup plan and attempt an endovascular revascularization. Long-term patency of endovascular revascularization will be poor because it's a Trans-Atlantic Inter-Society Consensus (TASC) D SFA lesion, the popliteal artery is occluded, there is a trifurcation occlusion, and the patient has had multiple previous failures. If I get a decent endovascular revascularization, I would not expect it to last more than 3 to 6 months, even with anticoagulation and antiplatelet agents. However, it may support toe amputation.

This would be a good case for randomization in the BEST CLI trial, and in our practice, we would try to do that. This can be approached with either open surgery or an endovascular approach. The likelihood of technical success at recanalization is high but not 100%. If we did not randomize, I would offer endovascular first. The fact that the patient has already had a failed bypass makes me less enthusiastic about offering bypass now, and I would save that as an absolute last resort.

After two failed attempts, worsening of dead tissue burden, and rest pain keeping her awake at night, this patient is probably suffering psychologically and likely has malnutrition. This should be addressed. I would see

if I could obtain any of the previous angiograms to see what the popliteal artery and runoff used to look like. This might help when passing wires blindly through "no man's land." I would also review the operator's notes from the bypass, as well as the history, to try to determine when the patient underwent bypass. In the off chance that it was a couple of weeks prior to this presentation, I may look for it and see if can be recanalized/lysed. However, based on the case description, I am thinking there is a low chance for this option.

I would use a contralateral femoral approach, utilizing a 6-F X 45-cm up-and-over Pinnacle Destination guiding sheath (Terumo Interventional Systems). I would make a transluminal attempt, especially because there are occluded stents that are not easy to go around using a subintimal approach. I would use a Hi-Torque Command guidewire (Abbott Vascular) or a V-18 ControlWire guidewire (Boston Scientific Corporation) supported by a CXI CTO support catheter (Cook Medical) and use a drilling technique to recanalize the occluded SFA and popliteal arteries. If friction were to become too severe to advance the wire and CTO catheter, I would not hesitate to start ballooning to create a channel. Friction/resistance to advancement would likely be significant in this case, because this is true multilevel disease and access is contralateral.

If there is minimal resistance to the wire, suggesting a significant thrombus burden, this might be one of the rare cases where I would stop attempting to recanalize and initiate thrombolysis with tissue plasminogen activator. One caveat is that this is really difficult for patients with true rest pain because they cannot be still and stay supine. In general, I would go as far as possible antegrade with the wire and support catheter. If support is not adequate, especially because the occluded distance is quite far, I would back up the wire and CTO catheter with a long, low-profile, 4-F sheath. If I end up subintimal when

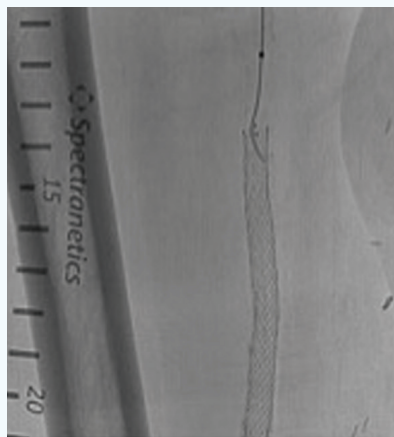


Figure 5



Figure 6

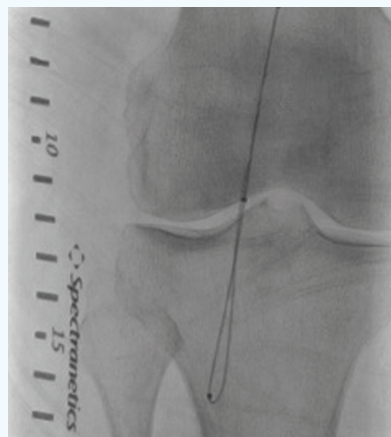


Figure 7

the wire is distal to the stents, I would just keep going. However, when this occurs in the popliteal and trifurcation, there is a place at every little branch where the subintimal wire can wander away from the main arterial structures. If I could drill directly into the peroneal artery or if the wire reenters the peroneal artery (although the likelihood is small), that would be best. I would be ready to perform retrograde puncture of the peroneal artery in the proximal portion of lower leg; I would not puncture it distally. If this plan does not work, it would be best to preserve the mid-distal peroneal artery as a bypass target.

If the wire cannot reenter from an antegrade approach or it goes subintimal and away from the popliteal and trifurcation, I would do a retrograde puncture. It would be best to make the wires rendezvous in the popliteal artery, if possible. After I have a wire across the whole lesion, I would dilate the entire distance with a plain or scoring balloon. Another option for the occluded stents is laser atherectomy. If it is hard or calcified, I would use a scoring balloon. For the reconstruction, I would lean toward using a DCB with spot stenting, especially in the SFA-popliteal region, as DESs have already failed in the SFA in this patient. With limited runoff, the use of stents or a long-segment Viabahn stent graft (Gore & Associates) would be at a disadvantage. The popliteal and tibial arteries are too small for the available DCBs, and it's not a great area for stents, so I would lean toward percutaneous transluminal angioplasty (PTA) plus bailout stenting. If there was severe dissection in the tibioperoneal trunk/proximal peroneal, I would use a coronary DES.

Dr. Das: I agree with the results of angiography and would try to recanalize the SFA and the single visualized vessel first. The peroneal artery appears to fill the dorsalis

pedis artery via the collaterals. I wouldn't try to attempt BTK revascularization all in the same sitting. I would have used laser for the in-stent segment, which is a personal preference and based on the EXCITE-ISR trial, followed by DCB use. I would obtain dorsalis pedis access to recanalize the anterior tibial artery in a retrograde fashion by using the CART technique or place the Outback reentry catheter (Cordis, a Cardinal Health company) into the retrograde balloon if unsuccessful. I agree with DES implantation at the anterior tibial occlusion if the patient is a candidate for longer-term (> 6 months) dual antiplatelet therapy.

Dr. Lookstein: I would likely bring the patient back in 2 weeks and perform a reconstruction of the anterior tibial using retrograde access. I am very liberal with DES BTK, so I would have performed prolonged long balloon inflation of the entire anterior tibial artery once it was crossed. Any abnormal results would be "tacked up" with a coronary DES. I typically place a 4-mm DES at the origin of the anterior tibial and tibioperoneal trunk, then use a 3.5-mm DES in the proximal calf anterior tibial artery and a 3-mm DES in the mid-calf and closer to the ankle.

CASE CONTINUED

The patient does well, and the limb is salvaged (Figures 8–11). Her gangrene has not progressed, but pain persists with near-rest pain. She returns to the angiography suite for further therapy. A decision is made to proceed with a dual antegrade and retrograde approach, which is accomplished with a double-balloon technique and fenestration of the CTO to allow passage of an antegrade wire to the distal segments. A 3.5- X 38-mm coronary DES (Xience, Abbott Vascular) is placed in the origin of the anterior tibial artery, and distal PTA is performed with a tapered 2- to 2.5-mm X 210-mm Pacific



Figure 8



Figure 9



Figure 10

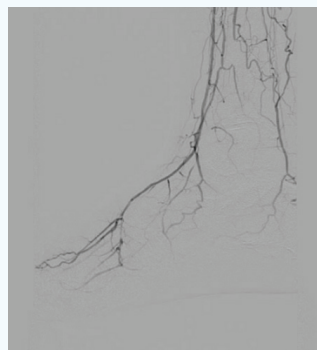


Figure 11

Plus balloon (Medtronic) with return of in-line flow to the foot and a palpable pulse.



What is your opinion regarding final results and treatment approach?

Dr. Schneider: If there is peroneal runoff, I would quit there and see how the foot does. The peroneal artery reconstitutes the dorsalis pedis artery and may be adequate. I would be strongly tempted to “touch up” residual stenosis or dissection anywhere along the SFA or popliteal artery. Given that this is such a long reconstruction, many technical defects will not be tolerated and will tend to cause treatment failure. If there is distal access, it likely does not matter too much where the rendezvous is undertaken, as long as it is somewhere along the occlusion. The challenge with the anterior tibial is the angulated course of the proximal artery. A wire coming from antegrade has to be steered into the anterior tibial artery, but then loses pushability due to the turn from the popliteal artery into the anterior tibial artery. A rendezvous somewhere in proximal to mid-anterior tibial is usually best. Based on the study by Schmidt et al, full-segment PTA of the anterior tibial artery

resulted in a 3-month patency rate of 30%.¹ I would also address the foot with early amputation of the affected toes as soon as possible while you have a good result.

Dr. Das: Rest pain and threatened limb loss require attempted intervention when distal targets can be identified (no matter how poorly filling). In this case, the peroneal and dorsalis pedis arteries were visualized in a very compromised inflow, which makes one assume that the vessels are underfilled and probably much more than the initial angiogram shows. The improvement in rest pain allows one to more thoughtfully discuss options, including amputation. Long-term success for patency is poor in this case but may be significantly improved for limb salvage. Follow-up duplex ultrasonography and close clinical follow-up are imperative. If wound healing slows after initial improvement, angiography should be repeated, not just duplex ultrasonography, but I usually perform both to avoid being surprised in the lab.

Dr. Lookstein: My ideal end result for any case of critical limb ischemia with gangrene is to have a palpable pedal pulse in the foot.

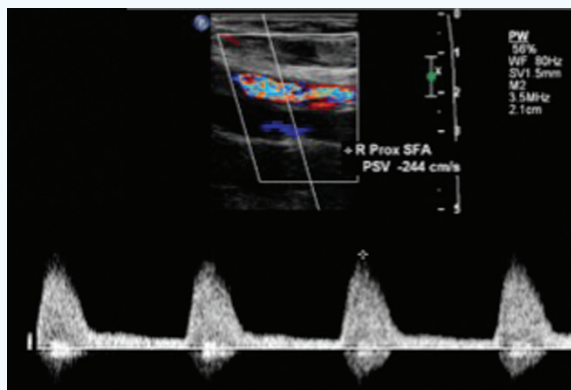


Figure 12

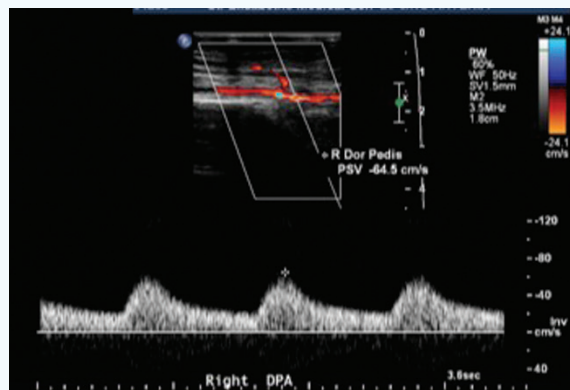


Figure 13

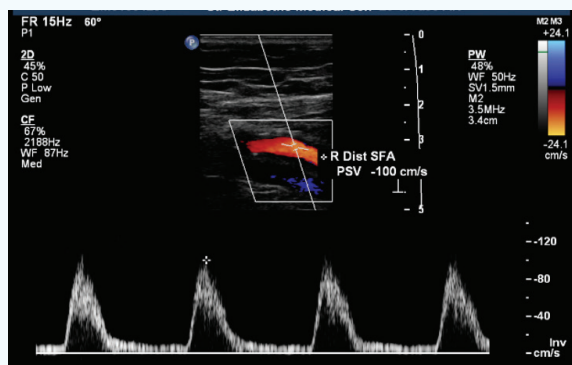


Figure 14

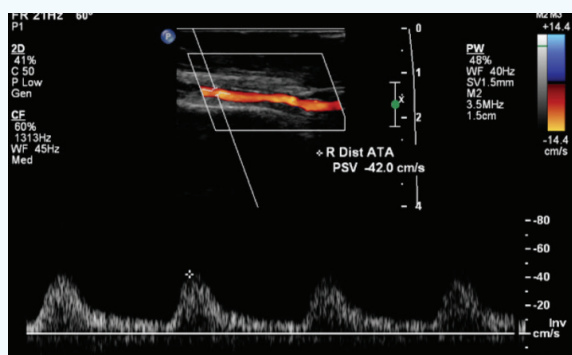


Figure 15

CASE CONCLUSION

The patient is doing well at 4 months postprocedure. Her limb rest pain has resolved, and she undergoes uneventful toe amputations of digits 2 and 3 of the right lower limb. Her follow-up duplex ultrasound shows outflow velocity in the forefoot to be > 70 cm/sec with an ABI of 0.65 on the right side. Additionally, at 6 months, her latest ultrasound shows continued improvement in the limb status with an ABI now of 0.83 and distal velocity in the anterior tibial artery of 43 cm/sec (Figures 12–15).

SUMMARY

This case demonstrates the unique variables that peripheral vascular patients may or may not present with in their risk of limb loss. Many critical limb ischemia patients are treated either via a surgical or endovascular approach but require repeated interventions. Clearly, short-term success may be limb salvage, but the long-term successes are murky at best to determine. The data for inflow disease using DES and DCB are very good.^{2,3} What's at issue remains the inability for a patient, such as this case patient, to be a candidate in any of these trials, leaving physicians to infer the possible outcome based on the ongoing data. Further, with the addition of this patient's outflow issues and gangrene, currently, the BEST

CLI trial would be the only place to review this specific patient's outcomes. Critically, in the BEST-CLI trial, the inflow and outflow require treatment at the time of the index procedure, which may make some endovascular specialists leery of doing too much at once.

It is clear is that despite optimal revascularization and "success," a successful long-term outcome here is challenging. Early and frequent evaluations for surveillance are mandatory. The issue of restenosis needs to be addressed, and reintervention should take place early in the next year to give this patient the best chances of limb salvage and symptom relief and prevent further tissue loss. ■

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