WHAT WOULD YOU DO?

An Extensive, Calcified CTO in the Superficial Femoral Artery

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CASE PRESENTATION

A 74-year-old woman presents with a 2-week history of ischemic pain and ulceration of the left foot. CTA shows an extensive, calcified chronic total occlusion (CTO) of the superficial femoral artery (SFA) reconstituting the P1 segment of the popliteal artery (Figure 1).

Cardiovascular risk factors include end-stage renal disease, insulin-dependent diabetes mellitus, hypertension, coronary artery disease with prior myocardial infarction and coronary artery bypass grafting (CABG), and known carotid artery stenosis with previous bilateral carotid endarterectomy. She also has a recent smoking history. Medications include aspirin 81 mg, labetalol 200 mg twice daily, doxazosin 4 mg at bedtime, amlodipine 5 mg daily, and recent amoxicillin clavulanate.

On physical examination, there are bilateral carotid endarterectomy scars. Femoral pulses are 1+ bilaterally. Popliteal and posterior tibial pulses are Dopplerable. Dorsalis pedis pulses are not audible. Superficial ulcerations are noted in the left foot in the digits. Capillary refill is impaired bilaterally. Both feet are slightly cold. Brittle nail beds are also noted, and there is evidence of hair loss and atrophy in both legs.

Would you treat this patient with bypass, endovascular therapy, or medical management, and what preprocedural workup guides this decision?

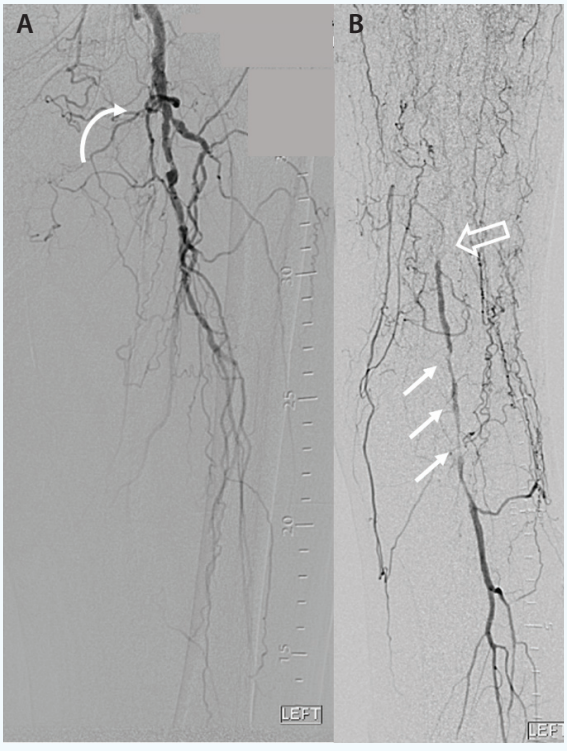

Figure 1. Initial angiogram demonstrates a flush CTO of the left SFA beginning at the ostium (A) (curved arrow) and reconstituting at the adductor canal (B) (open arrow). Additional hemodynamically significant stenosis in the P2 popliteal segment (B) (straight arrows).

Dr. Miller: Given the presence of toe ulcerations, I would strongly consider revascularization. Because of the patient's history of CABG, I would be concerned that she may not have adequate venous conduit for bypass grafting. This would shift her more toward endovascular options. She would also require medical optimization with the addition of a statin and possibly an angiotensin-converting enzyme inhibitor. Smoking cessation, diabetes control, and exercise (if possible) may be considered.

Dr. Montero-Baker: Most of our patients receive endovascular therapy as first-line therapy. The patient has a clear past medical/surgical history that puts her at greater risk for open repair. It is likely that any viable conduit was used for her CABG, so you'd be dependent on nonideal conduits for a below-the-knee popliteal anastomosis (ie, prosthetic, cadaveric, spliced vein). We are currently enrolling patients into a very interesting study in which we assess the level of frailty preoperatively by means of advanced motion sensors. This is something we believe should help the clinician to better tailor therapy in the future.

Dr. Varghese: This patient presents with critical limb ischemia of the left lower extremity with evidence of minor tissue loss. Given the presence of skin ulceration and vascular compromise, I would pursue an endovascular-first approach and attempt to revascularize the occluded left SFA. Surgical bypass is certainly a good option, but given her significant comorbidities such as coronary artery disease and prior CABG, her cardiac risk for surgery would be elevated. Additionally, her history of end-stage renal disease and diabetes could delay or complicate postoperative wound healing and overall recovery.

The preprocedural CT angiogram is a great tool to lay out a plan of attack. Three factors are important to me. First, the extensive length of the CTO makes intraluminal crossing less likely and favors subintimal crossing. Second, the severity of vessel calcification plays a role in determining antegrade crossing success. Third, given the above characteristics, a retrograde access is highly likely and, therefore, the patency of the infrapopliteal vessels at baseline would be of interest.

In general, what is your initial treatment (including surgical or device choices) for long-segment SFA CTOs and what data support your approach?

Dr. Montero-Baker: I strongly believe these long lesions should be treated with a regular balloon. This first percutaneous transluminal angioplasty (PTA) will give the operator very important feedback as to the nature of the disease and the areas of most complexity. After the first angioplasty, one will be able to determine the presence of complex dissections and/or plaque that may be unresponsive to simple mechanical modulation. To follow, a tailored approach to vessel preparation then becomes more targeted—focal atherectomy, focal force balloons, and focal lithoplasty. To finalize, drug-coated technology, a scaffold, or a combination of both may be useful to improve primary patency. Despite the advances in drug-delivery devices (ie, drug-coated balloons [DCBs]), the reality is that with lesions of such complexity, odds are that some degree of scaffolding will be needed. Most DCB global registries have more than 25% to 40% bailout stenting when dealing with TransAtlantic Inter-Society Consensus (TASC) C/D lesions. The ideal stent in these scenarios is likely one with low in-stent restenosis rates, vasculomimetic properties, and drug elution.

Dr. Varghese: My initial strategy for a long-segment SFA CTO involves device-based crossing. A recent study within the XLPAD registry demonstrated that the use of dedicated CTO crossing devices provided significantly higher technical success, as well as lower reintervention and amputation rates.[1] I have had success using the Ocelot catheter (Avinger, Inc.), which uses optical coherence tomography guidance. If a device approach fails, I switch to a wire/support catheter-based system. If all antegrade attempts fail to cross the occlusion, I quickly switch to a suitable retrograde access (eg, tibiopedal or popliteal artery).

Once I have successfully crossed the CTO, I typically use atherectomy to debulk and modify plaque. In this case with heavy calcification, I would favor orbital (Diamondback 360, Cardiovascular Systems, Inc.) or hybrid atherectomy (Phoenix atherectomy system, Philips Volcano). For definitive therapy, I prefer using DCB technology based off the IN.PACT SFA trial data. If any resistant lesions or flow-limiting dissections are present after DCB, then I would use a short self-expanding nitinol stent.

Dr. Miller: My initial approach would involve engagement of the proximal occlusion with a crossing catheter and guidewire with subintimal recanalization of the CTO. I would focus on early reentry into the true lumen of the popliteal artery, which could limit the length of intervention. This would be followed by PTA and DCB with spot stenting for refractory lesions or focal flow-limiting dissection flaps.[2] Targeted in-line flow to the affected angiosome would need to be confirmed given the history of toe ulceration.

If you were to treat this lesion using endovascular therapy, what would be your preferred access? When would you use an alternative or secondary access, and what would be your approach and technique?

Dr. Varghese: For an extensive SFA occlusion, I would start by having my staff sterilely prepare the treatment limb from groin to toes in anticipation of using a second retrograde access. I typically start with a contralateral "up-and-over" approach to engage the diseased segment in an antegrade fashion. If antegrade crossing of the lesion is not successful, I would rapidly change strategies with a retrograde tibiopedal access using ultrasound guidance and a dedicated pedal access kit, including a 4-F microsheath with a hemostatic valve (Micropuncture Pedal Access Set, Cook Medical). Once access is secured, retrograde techniques can be employed with device- or wire-based systems. If the antegrade and retrograde wires cannot be positioned adjacent to each other for controlled antegrade and retrograde subintimal tracking (CART) or reverse CART techniques, then direct SFA retrograde access may be considered. This is usually fluoroscopically guided using landmarks such as heavy calcium or an occluded stent segment as a guide for needle access.

We conducted a study (FACTOR) at our institution that prospectively examined 150 SFA CTOs and assigned each CTO lesion a score based on lesion characteristics and complexity. We also developed a crossing algorithm to augment procedural success. Our results indicated that with increasing lesion complexity (a higher CTO score), additional access sites were required to maintain high crossing success rates. This predictive SFA CTO score may aid in preprocedural planning and determine whether retrograde access may be required.

Dr. Montero-Baker: In this case, my preferred access would be antegrade common femoral artery access. For secondary access, I would use a retrograde high anterior tibial or distal popliteal artery approach.

Dr. Miller: My approach would include contralateral right femoral access with the left foot prepped for potential retrograde access if required to reestablish in-line flow to the area or toe ulceration. I would use retrograde access in two situations: (1) if I was unable to deliver a reentry device over the bifurcation if true lumen access could not be obtained and (2) if sufficient mechanical advantage to cross the occlusion was not possible from the contralateral access. A third use of retrograde access would be if targeted angiosome reperfusion was not obtained from the contralateral femoral access intervention.

After treatment, how do you perform surveillance, and what would be your expected rates of restenosis and target lesion revascularization for this patient?

Dr. Montero-Baker: The patient would return for follow-up at 2 weeks and at 3, 6, and 12 months. Restenosis rates are hard to predict. In my experience, they tend to be more focal and less extensive then when I used a laser-cut stent and full metal jacket approach. Our trigger for reintervention is lesions with peak systolic velocity > 300 cm/s and ratios of 3.0 and above. This ultimately represents anywhere from 20% to 40% of patients with TASC D lesions at 12 months. Our usual treatment would be laser atherectomy plus DCB. The rate of a second significant restenosis after the latter therapy is much less.

Dr. Miller: I would follow with a combination of noninvasive ultrasound and assessment of symptoms. At 1 month, we would acquire noninvasive imaging including toe pressures and assess the status of her ulcers. I would follow her ulcers and clinical examination until complete healing has occurred. If ulcers have poor progression of healing at 3 months, the toe pressures are repeated. If the ulcers worsen (pressure < 30 and toe-brachial index < 0.7), reintervention is performed. Her expected primary patency is around 70% with a clinically driven target lesion revascularization of 84%.[3] The patient's reintervention is primarily clinically driven by healing status of her ulcers and the presence or absence of ischemic rest pain.

Dr. Varghese: After successful therapy, I recheck resting ankle-brachial indices and clinically reevaluate the patient at 4 weeks postprocedure. Provided the patient has symptomatically improved and commenced wound healing, I would perform surveillance every 3 months with clinical evaluation and noninvasive testing. The expected rate of restenosis following successful revascularization of a long SFA CTO would be 10% to 15% in today's era of drug-eluting technologies. Target lesion revascularization would be in the range of 5% to 10% over 12 months. Several factors may influence these outcomes, including severity of vessel calcification, infrapopliteal vessel outflow, baseline length of the occlusion, and prior restenosis.

TREATMENT COURSE

This was a particularly challenging case of a densely calcified SFA CTO. In years past, we may have approached this case for surgical bypass, but diffuse calcification was seen as a limitation to a suitable bypass target, and we have developed extensive experience and comfort

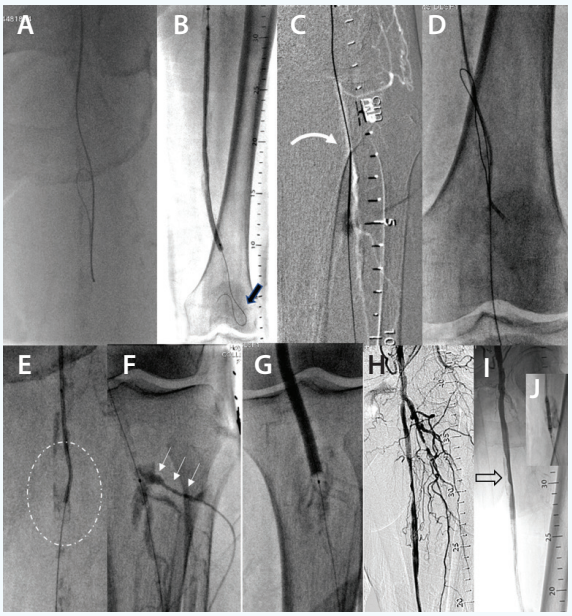

Figure 2

in treating even long-segment SFA disease with endovascular therapy. For occlusions such as in this case, our primary strategy is to perform direct subintimal recanalization. Spontaneous reentry at the point of distal arterial reconstruction occurs in the majority of cases, and the remainder can be completed with a reentry device. The subintimal tract is dilated, and if satisfactory, DCB angioplasty is performed at the arterial exit and entry sites. For residual exit/entry disease, focal stenting is preferred, and long scaffolds (often stent grafts) are reserved if the entire subintimal tract is compromised.

Our initial approach from a contralateral femoral access, utilizing a 7-F crossover sheath, is to engage the SFA occlusion. Often, this is done with the tip of the sheath dilator, or using a long 5-mm hydrophilic balloon catheter. Our preferred wire is a 260-cm-long, 0.035-inch Glidewire Advantage (Terumo Interventional Systems). With gentle forward pressure, a wire loop is created (Figure 2A), allowing the advance of the wire and hydrophilic balloon together (Figure 2B). The wire is repeatedly retracted and advanced during crossing to maintain a short loop configuration, particularly at the site of desired reentry. In this case, and unusual in our experience, the dense arterial mural calcification prevented spontaneous or device-assisted reentry (Figure 2B, arrow), and a retrograde access was deemed necessary to complete the case. Our preferred name for this method is a "rendezvous" procedure, although other commonly used terms include SAFARI (subintimal arterial flossing using antegrade and retrograde intervention) and CART.

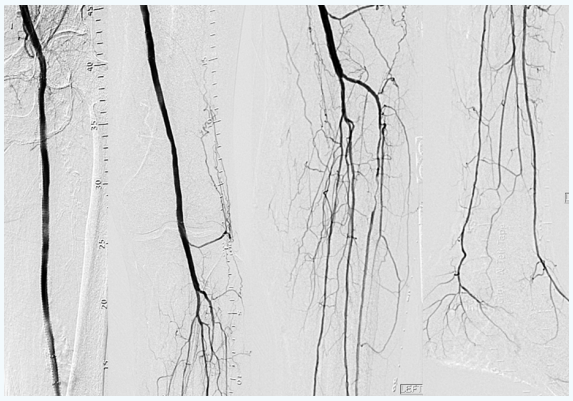

Figure 3

With the patient supine, we elected to perform an anterior popliteal artery puncture. Under roadmap guidance and with the fluoroscopy tube angled in an appropriate ipsilateral anterior oblique to create a window between the upper tibial and fibula, a 21-gauge needle is directed using standard technique into the popliteal artery, and a 0.018-inch shapeable tip stainless steel wire is inserted (Figure 2C, curved arrow). Catheters and wires are manipulated from both the antegrade and retrograde access sites to enlarge and eventually create a subintimal communication (Figure 2D). The retrograde wire is then directed off the vessel wall into an angled antegrade catheter (Figure 2E, dashed circle), allowing exteriorization and subsequent through-and-through wire access. A balloon catheter is then passed antegrade until the tip is in patent artery distal to the CTO, and the through-and-through wire is removed, allowing a new wire to be advanced in a forward fashion through the balloon and distal to the popliteal sheath. Hemostasis at the popliteal site is accomplished in two ways. First, the sheath is withdrawn while injecting contrast until it is just outside of the artery (Figure 2F, arrows). The antegrade balloon is advanced and inflated for balloon hemostasis for approximately 5 minutes (Figure 2G), at which time 3 mL of 1:1000 topical thrombin is injected outside of the artery.

After PTA, angiography showed restored SFA patency with residual flow-limiting recoil and dissection (Figure 2H), and a nested 6-mm Viabahn stent graft (Gore & Associates) was deployed, although arterial calcification limited full graft expansion in several areas (Figure 2I, open arrow). These areas were dilated using short 6-mm "focal force" balloons (Figure 2J, insert). Completion angiography showed an optimal result with restored unobstructed femoropopliteal flow and three-vessel runoff to the foot (Figure 3). The patient had complete healing of her wounds and resolution of clau-

dication, and duplex ultrasound surveillance at 1 and 3 months (thus far) show maintained patency. Further surveillance is planned at 6 and 12 months, with annual office visits thereafter unless there is additional interval clinical need. ■

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