What Are the Five Devices Your CLI Practice Can't Live Without?

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Approximately 40% of my practice deals with critical limb ischemia (CLI) patients. I perform 10 to 20 open operations and endovascular procedures for these individuals each month. I have tried many hydrophilic wires and have not found any to be as useful as the stiff Glidewire (Terumo Interventional Systems). This is my "go-to" wire for all SFA chronic total occlusion (CTO) crossings. I find that I am successful in crossing long-segment CTOs in more than 90% of cases with this wire and a catheter alone. I could not imagine my practice without this device.

The Quick-Cross catheter (Spectranetics Corporation) was the first dedicated support catheter for CTOs, in my opinion, and although many vendors have now come out with competitive versions, I find this catheter to be invaluable in my practice in crossing SFA, popliteal, and tibial lesions.

The 4-F Micropuncture set (Cook Medical) allows a smoother transition between the 3-F inner dilator and the 4-F outer dilator. It tends to push through scarred groins with ease in both antegrade and retrograde femoral access, and use of the 3-F inner dilator has facilitated both pedal and popliteal artery access for retrograde crossing of long-segment CTOs, alleviating the need to place a sheath.

The 0.014-inch PT2 wire and now the 0.014-inch V-14 wire (Boston Scientific Corporation) are very steerable with great torque responsiveness, which aids in steering through tibial occlusive disease. When used from a contralateral femoral approach, most coronary wires will not spin or maintain good 1:1 torque responsiveness below the knee, especially when the iliacs are densely calcified, which tends to deform the crossing sheaths.

The Amphirion Deep 10-cm-long, 0.014-inch balloon (Medtronic, Inc.) revolutionized my approach to tibials, with long angioplasty balloons with long inflations that alleviate the need for stenting in most patients. The crossability of this balloon was unmatched until just recently, when most vendors came out with competitive dedicated balloons that are now ≥ 220 mm in length. The reduction in procedure length and radiation dosages is a great improvement.

Dr. Lyden is a VIVA Board Member; Advisory Board Member for Medtronic, Inc., Covidien, and TriVascular, Inc.; receives honoraria from Cook Medical, Cordis Corporation, Medtronic, Inc., Covidien, and Terumo Interventional Systems. He is involved in research trials for Lutonix, Inc., Cook Medical, Gore & Associates, Cordis Corporation, AtheroMed, Inc., and Possis, now Bayer Radiology and Interventional.

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In my practice, between a quarter and a third of all patients are treated for CLI, and the proportion is steadily increasing. The treatment involves femoropopliteal and below-the-knee (BTK) disease. Especially in the BTK treatment, major technological improvements have been accomplished, and my focus will be mainly on this arterial segment.

For the treatment of long lesions, long, low-profile balloons (length > 12 cm) are needed since they can provide a quick fix (ie, treatment with a single inflation).

I use 0.014-inch guidewires with a length of 300 cm. I recommend having a total of three to four wires available, including one so-called workhorse wire that will address the majority of the lesions, preferably with a tapered-down tip and good torque control to allow for navigation in tortuous anatomy. The other wires should be used in cases of total occlusion and have two or three different tip loads. I do not mention any specific brands here due to the variation in availability throughout the world.

Long introducer sheaths (4-F) with a length of at least 45 cm for antegrade procedures and at least 90 cm for procedures performed in crossover are useful. Especially in complex cases, working with long sheaths will increase control and pushability of guidewires and balloons.

In case of antegrade recanalization failure, a pedal access kit is a must to increase the technical success rate of these sometimes-complex procedures.

An ultrasound system should be available to facilitate pedal and popliteal access. I prefer ultrasound-guided puncture to minimize puncture-site complications and reduce radiation exposure to the operator.

Dr. van den Berg has disclosed that he has no financial interests related to this article.

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My CLI practice is very active and includes the types of patients we have all come to expect in such a practice, from those with rest pain to severe CLI, significant tissue loss, and those who are at risk of amputation. We perform nearly 500 procedures per year in my practice, and a large proportion are CLI patients. We believe there are several devices that we must have in this type of practice to offer our patients the best treatment available.

We need the ability to have antegrade access for distal lesions that require the shortest route to the targets. We employ the microneedle puncture systems, which are incredibly useful for antegrade access, and more importantly, for pedal access. Further, the use of an imaging system for access remains very important, particularly for distal access patients.

For retrograde access, I prefer to use either a 55- or 90-cm Raabe or Ansel style sheath (Cook Medical), or for antegrade access, an Arrow sheath (Teleflex Incorporated). We require both the 0.035-inch Glidewire (Terumo Interventional Systems) for proximal CTOs and a 0.014-inch specialty wire, such as in the Asahi family of wires (Abbott Vascular) and the 0.018- and 0.014-inch V series (Terumo Interventional Systems).

Crossing devices are very important. As a default, we generally use a simple wire strategy with a 0.035-inch Glidewire through a surrogate support catheter for almost all proximal occlusions, although many times, we have used other CTO devices including Wildcat (Avinger, Inc.), TruePath (Boston Scientific Corporation), and Crosser (Bard Peripheral Vascular, Inc.). For proximal occlusions that are difficult to cross, we prefer the Outback device (Cordis Corporation) for reentry.

From an interventional standpoint, once we cross the targets, we generally prefer to use a series of balloons that are long and deliverable for tibial patients who are invariably seen for CLI. We favor the Medtronic Invatec balloons and have used the tapered balloons many times for limited inflations and prolonged treatment times for optimal angioplasty. For those stubborn lesions, we prefer the force-focused dilation of AngioSculpt balloons (AngioScore, Inc.). Ultimately, in terms of balloon technology, we would all love to see the drug-coated balloons come to the US market to give our patients the same potential for patency that our European colleagues enjoy.

We also cannot live without atherectomy devices for our CLI patients. We use both directional (SilverHawk [Covidien]), which has been our default therapy for infrapopliteal disease, and rotational (Jetstream [Bayer Radiology and Interventional]) atherectomy, for calcific lesions needing arterial compliance changes given the aspiration from this device and the ability to distally protect with a fixed filter design.

Stents remain a bailout device for the infrapopliteal segments (unless they are very focal in disease) that are either difficult to dilate, have a dissection after percutaneous transluminal angioplasty, or have significant recoil. For these cases, we prefer some form of drug-

eluting stent such as the Xience coronary stent (Abbott Vascular).

Dr. Garcia is on the advisory board and performs research for ev3 Inc./Covidien and iDev Technologies, is on the advisory board for Pathway/Medrad and Angiosculpt, and is a consultant for Covidien and Arsenal Medical. He has equity interests in Scion Cardio-Vascular, Arsenal Medical, TissueGen Medical, Primacea, and CV Ingenuity.

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My lab performs approximately five CLI interventions each week. Long (8–22 cm) infrapopliteal balloons have been the most revolutionary technology in my CLI practice. They are available from numerous vendors in both over-the-wire and rapid-exchange platforms. Now, even long occlusions can be treated in minutes. This technology has led to fewer dissections and less need for bailout stent placement.

Reentry catheters have advanced the treatment of femoropopliteal occlusions. With the use of reentry catheters, the technical success of crossing long occlusions approaches 100%. This allows almost every patient with CLI to be treated with endovascular techniques.

Increasingly, patients are undergoing endovascular procedures in the setting of single- or no-vessel continuous runoff to the foot at the start of the procedure. Distal embolic filter systems allow endovascular procedures to treat long stenoses or occlusions using multiple technologies without fear of an embolic complication. My lab routinely uses distal filters for patients with severely compromised runoff.

Support catheters are absolutely necessary to successfully cross long occlusions. The most common product we use is a 0.018-inch-lumen device to recanalize both above-the-knee and below-the-knee circulation.

In addition, 0.014-inch CTO guidewires allow for the successful crossing of even long infrapopliteal occlusions. These dedicated CTO wires allow for successful interventions below the knee and even below the ankle.

Dr. Lookstein currently serves as a consultant to Cordis Corporation and Medrad Interventional, now Bayer Radiology and Interventional, and receives speaking honoraria for educational lectures from Boston Scientific Corporation.

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I perform approximately five to 10 CLI procedures per month. These include patients with rest pain and tissue loss. For the most part, patients present in a semiurgent manner, oftentimes with a nonhealing ulcer that is infected. Occasionally, patients present emergently.

I utilize low-profile access equipment such as the 5- and 6-F Destination sheaths (Terumo Interventional Systems) when coming from a contralateral approach. These sheaths are very flexible, and almost all superficial femoral, popliteal, and tibial artery procedures can be accomplished with them. I use a combination of 0.035- and 0.014-inch wires. I find the Quick-Cross catheter (straight and select) (Spectranetics Corporation) extremely useful for tracking through very stenotic lesions or occlusions.

For lesions in the superficial femoral artery (SFA), I generally use the LifeStent (Bard Peripheral Vascular, Inc.) because it is easy to deliver precisely. It has a broad range of sizes, and I have observed favorable results with this stent. If I have a very calcified or "shaggy" lesion, I will place a Viabahn stent (Gore & Associates) to fully exclude the diseased vessel segment.

In tibial lesions, I generally use angioplasty alone. My balloon of choice is the Amphirion (Medtronic, Inc.). It is low profile, easy to track, has a broad range of sizes, and has demonstrated excellent results.

I have found the Pioneer catheter (Medtronic, Inc.) to be terrific for reentry. Although I can almost always reenter with just a catheter and wire, sometimes, this is not successful, and I have always been able to reenter with the Pioneer catheter. The use of intravascular ultrasound also allows for precise reentry. I have also used the Crosser (Bard Peripheral Vascular, Inc.) to cross chronic total occlusions; I have found this useful in establishing a path through the true lumen. This is especially helpful for avoiding subintimal planes and potentially dissecting the runoff target vessel.

Dr. Woo is a paid consultant to and received grant/research funding from Gore & Associates, Medtronic, Inc., and Bard Peripheral Vascular, Inc.

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At our practice, we treat an average of four CLI patients per week. In treating these patients, an equally important consideration is what else we needed that we do not currently have.

The first step is successful access with the tip of the sheath or guide catheter close to the target vessels. Beyond that, good wires are fundamental to the success of the procedure. The complexity and lesion variability of tibial vessels in CLI patients often require the use of more than one specialty wire. For below-the-knee applications, we prefer to start with a Whisper wire (Abbott Vascular) for both CTOs and long diffuse diseased segments. In densely calcified CTOs, our backup wire is either the Hydro ST (Cook Medical) or the Asahi Confianza (Abbott Vascular). When navigating through a string of calcified high-grade stenoses where a "finesse" wire is more appropriate, the backup wire can be the Pilot (Abbott Vascular) or Transcend EX (Boston Scientific Corporation). I also recommend trying the Synchro standard guidewire (Boston Scientific Corporation) when one-to-one torqueability is an absolute must; however, this wire is not as good of a "rail" for BTK arteries as the others that were previously mentioned. Additionally, I find the Runthrough 0.014 wire (Terumo Interventional Systems) to be a good workhorse with a very durable tip.

In infrapopliteal CTOs, we prefer to use support catheters rather than balloons to navigate through the occlusions. A low-profile balloon with good trackability and pushability is another device fundamental to success in these vessels. The two most common types of balloons we use include the Armada (Abbott Vascular) and the Nanocross (Covidien) lines. The use of the over-the-wire Quantum Maverick (Boston Scientific Corporation) as a facilitator in tight lesions resistant to crossing with other balloons is not uncommon in our patient population.

Finally, front-cutting atherectomy devices such as the Diamondback (Cardiovascular Systems Inc., St. Paul, MN) or Jetstream (Bayer Radiology and Interventional, Indianola, PA) can be timesaving adjuncts, which in our lab are used as enabling devices rather than as the primary therapeutic ones.

Dr. Razavi is on the scientific/strategic advisory boards for Abbott Vascular, Altura Medical, Inc., Arsenal Medical, Covidien, TriVascular, and Vessix Vascular, Inc. He also receives research and financial support from Bard Peripheral Vascular, Inc., Cordis Corporation, Idev Technologies, Inc., and Gore & Associates.

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We perform at least one CLI intervention per week. The procedures carry a significant sense of urgency compared to elective cases. The patient is at risk of limb loss, and the surgical options other than amputation are often limited. We are usually confronted with CTOs below the knee. Our goal is to reestablish continuity, relieve pain, and promote wound healing.

The Asahi Confianza Pro 12 wire (Abbott Vascular) is a 0.014-inch wire with a 12.4-g tip load that crosses CTOs like no other. We use it with caution because of the risk of perforation, but we quickly move to this wire when less-aggressive wires fail. Once we have confirmed wire placement in the true lumen distally, we exchange for a conventional 0.014-inch wire with a less traumatic tip.

The Quick-Cross support catheter (Spectranetics Corporation) has a tapered tip, outstanding longitudinal rigidity, and calibration markers along the shaft for sizing. We use the 0.014-inch version for below-the-knee interventions.

The AngioSculpt balloon catheter (AngioScore, Inc.) has an excellent crossing profile and durability for multiple inflations. We commonly use this "focal force" scoring balloon to treat heavily calcified plaque in the tibial and peroneal branches. The 220-cm-length Savvy long balloon catheter (Cordis Corporation) allows for a single long inflation with a focal stent strategy that we favor. The Savvy is a workhorse product that we use in our lab.

Outside the US, the Xience Prime everolimus-eluting stent system (Abbott Vascular) is indicated for infrapopliteal use because of its demonstrated reduction of neointimal hyperplasia. We use the coronary-approved Xience Prime stent (same product) "off-label" as allowed by US Food and Drug Administration guidelines when faced with a suboptimal angioplasty or atherectomy result, particularly a severe dissection that is at risk for abrupt closure.

A top ten list (rather than a top five list) would include CTO devices, atherectomy devices, intravascular ultrasound, and other tools that are essential as well.

Dr. Foster lll receives honoraria from Abbott Vascular and Cordis Endovascular. He is also on the medical advi-

sory board for Boston Scientific Corporation and receives speakers' honoraria from Pathway Medical.

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We have a busy CLI practice with approximately four limb preservation interventions referred weekly, predominantly through our network of podiatrists and primary care physicians. These below-the-knee, and now below-the-ankle, interventions represent some of the most challenging cases for us, and success is heavily reliant on devices and systems dedicated to small vessels. In our practice, our standard "system" for tibial interventions starts with a contralateral 7-F or antegrade 5- or 6-F sheath through which we coaxially place a 4-F angled nontaper Glidecath (Terumo Interventional Systems.) and Renegade STC microcatheter (Boston Scientific Corporation). Initial lesion crossing is attempted with the Persuader-3, (3-g weight tip, Medtronic, Inc.) followed by the Persuader-6, (6-g weight tip) followed by Confianza wires (Asahi family of wires, Abbott Vascular). If intraluminal recanalization cannot be achieved or a subintimal technique is planned, this is accomplished with a 0.014-inch Glidewire (Terumo Interventional Systems).

Once lesions are crossed, interventions are done over a stiffer exchange wire (Thunder wire, or equivalent, Medtronic, Inc.). Low-profile long-length balloons are indispensible, and we use the Amphirion Deep balloon (Medtronic, Inc.) principally. Drug-eluting stents are a critical adjunct and our practice has good experiences with Endeavor stents (Medtronic, Inc.). Pedal access cases require dedicated ultrasound and 4-F or 5-F pedal access sets (Cook Medical). Plantar-pedal interventions are evolving; for these, we rely on 0.014-inch Whisper wires (Abbott Vascular) and Apex or Coyote balloons (Boston Scientific Corporation). Of course, tremendous variations exist, keeping interventions for CLI an exciting and technically challenging area of treatment. In summary, if I had to pick just five devices for CLI interventions: 0.014-inch Glidewires, Amphirion or equivalent balloons, Endeavor drug-eluting stents, Whisper wires, and pedal access sets. Happy intervening! ■

Dr. Rundback is a consultant to St. Jude Medical, Inc., Biotronik, Inc., Arstasis, Inc., ev3, Inc., Vessix Medical, and Abbott Vascular. Dr. Rundback also speaks on behalf of Boston Scientific Corporation, Terumo Interventional Systems, and Cook Medical.