A European Perspective: Valued Care and the Potential for CTO Credentialing

The current treatment landscape for complex superficial femoral artery lesions and recommendations for improvement.

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Peripheral artery disease (PAD) affects more than 200 million patients worldwide. Its prevalence has increased between 13% and 27% in the past decade.[1] As the population continues to age and obesity, diabetes, and tobacco use remain uncontrolled, the prevalence of PAD and critical limb ischemia (CLI) will increase exponentially. Although PAD can be asymptomatic and subclinical, it is associated with reduced functional capacity and quality of life when symptomatic and is a major cause of limb amputation in its most severe form.[2]

CLI patients typically have multilevel and multivessel involvement: 67% of patients present with femoropopliteal and infrapopliteal disease,[2] with mortality ranging from 25% to 30%, and a 30% major amputation rate within the first year of diagnosis.[3] Although surgical revascularization had been considered the standard treatment for femoropopliteal disease, endovascular therapy has become the preferred initial approach.[4] The success and durability of endovascular therapy for femoropopliteal disease have been limited by heavy plaque burden, calcification, and high prevalence of chronic total occlusions (CTOs). These factors make lesion crossing very complex and challenging, with a high rate of failure even after utilizing the most advanced technical strategies, leading to suboptimal revascularization results.[5]

COMPLEX LESIONS

The first step when treating symptomatic PAD is to define the vascular lesion location and vessel involvement, the presence of stenosis versus occlusions, and the presence of arterial wall calcifications. These factors impact the treatment approach (endovascular vs surgery). If using an endovascular approach, the strategies, success, and results can be affected in terms of primary patency. After lesion classification and considering clinical manifestations (claudication vs CLI) in relation to lesion type, a treatment approach can be determined.

The TransAtlantic Inter-Society Consensus (TASC) classification is the most widely used classification system for vascular lesions and categorizes lesions based on the combination of stenosis, occlusions, and lesion length.[6] Treatment recommendations (endovascular vs surgical) are provided based on the category. The Peripheral Academic Research Consortium (PARC) provides an alternative definition for vascular lesions based on lesion and vessel characteristics, which can be easily used during daily clinical practice.[7] Diameter stenosis is categorized as mild (< 50%), moderate (50%–69%), severe (70%–99%), and occluded (100%). Lesion length is divided into focal (≤ 1 cm), short (> 1 and < 5 cm), intermediate (≥ 5 and < 15 cm), and long (≥ 15 cm). The degree of calcification is defined as focal, < 180˚ (one side of vessel) and less than one-half of the total lesion length; mild < 180˚ and greater

than one-half of the total lesion length; moderate, ≥ 180˚ (both sides of vessel at same location) and less than one-half of the total lesion length; and severe, > 180˚ (both sides of the vessel at the same location) and more than one-half of the total lesion length.

TASC C and D lesions, or the severely calcified long occlusions from the PARC classifications, are considered the most challenging cases in the femoropopliteal segments because they demand advanced technical strategies, specific devices, and more contrast medium and operator time.[6-8] A specific performance goal should be established for treatment outcomes in these complex superficial femoral artery (SFA) lesions to determine an acceptable treatment success rate.

The objective performance goal (OPG) suggested by Rocha-Singh et al[9] focused on an efficacy OPG of primary patency ≥ 66% at 12 months and a safety OPG of freedom from death from any cause, freedom from target lesion revascularization, and freedom from amputation ≥ 88%. Conte et al[10] suggested different OPGs, considering any major adverse limb event; major adverse limb event plus perioperative death; major cardiovascular event; amputation; amputation-free survival; reintervention or amputation; reintervention, amputation, or stenosis; and any cause of death.

These OPGs may be used as metrics for success and to measure improvement over time by analyzing the reduction in complication rates, improvement in patency, amputation-free survival, and reinterventions. Specifically, reinterventions related to unsuccessful attempts or new occlusions that have been unsuccessfully treated may increase the patient's risk for new interventions and increase procedure cost.

HOW TO MANAGE COMPLEX LESIONS

The endovascular approach for the treatment of long, severely calcified CTOs in the femoropopliteal segment has grown in acceptance, even though the location remains a controversial indication for the therapy and long-term durability results. This is evident in multiple clinical trials describing various therapies used to treat long SFA lesions, such as mimetic technologies, drug-coated balloons (DCBs), and drug-eluting stents (DESs).[5,8-12]

Despite these trials and results, endovascular management of long, calcified CTOs in the femoropopliteal segment remains very challenging. In our experience at Abano Terme, crossing these lesions is very complex, frequently mixes antegrade and retrograde access (up to 35% of cases),[5] is time consuming and technically demanding, and places patients in an aggressive and long procedure with a high volume of contrast medium and a high dose of radiation.

HOSPITAL IMPACT ON MANAGEMENT OF COMPLEX SFA CTOs

A physician's skills are directly related to the number of complex patients he or she has treated and the number of successful procedures performed throughout his or her career. Guidelines from Germany and Italy state that after general and clinical orientation, a local center's expertise is very important and should directly influence procedure decisions.[13,14] Therefore, a center's volume of complex SFA CTOs treated by endovascular approach would impact the expertise and skills of the center's physicians.

To our knowledge, no society in Europe has described center expertise or published the number of complex SFA CTOs treated by endovascular approach by center. As such, it is difficult for general practitioners and patients to properly select where and who should use an endovascular approach for the treatment of a complex SFA CTOs. In addition, if a hospital or physician inexperienced with an endovascular approach attempts the procedure but fails, more experienced physicians may later encounter a more complex situation because of the previous failed

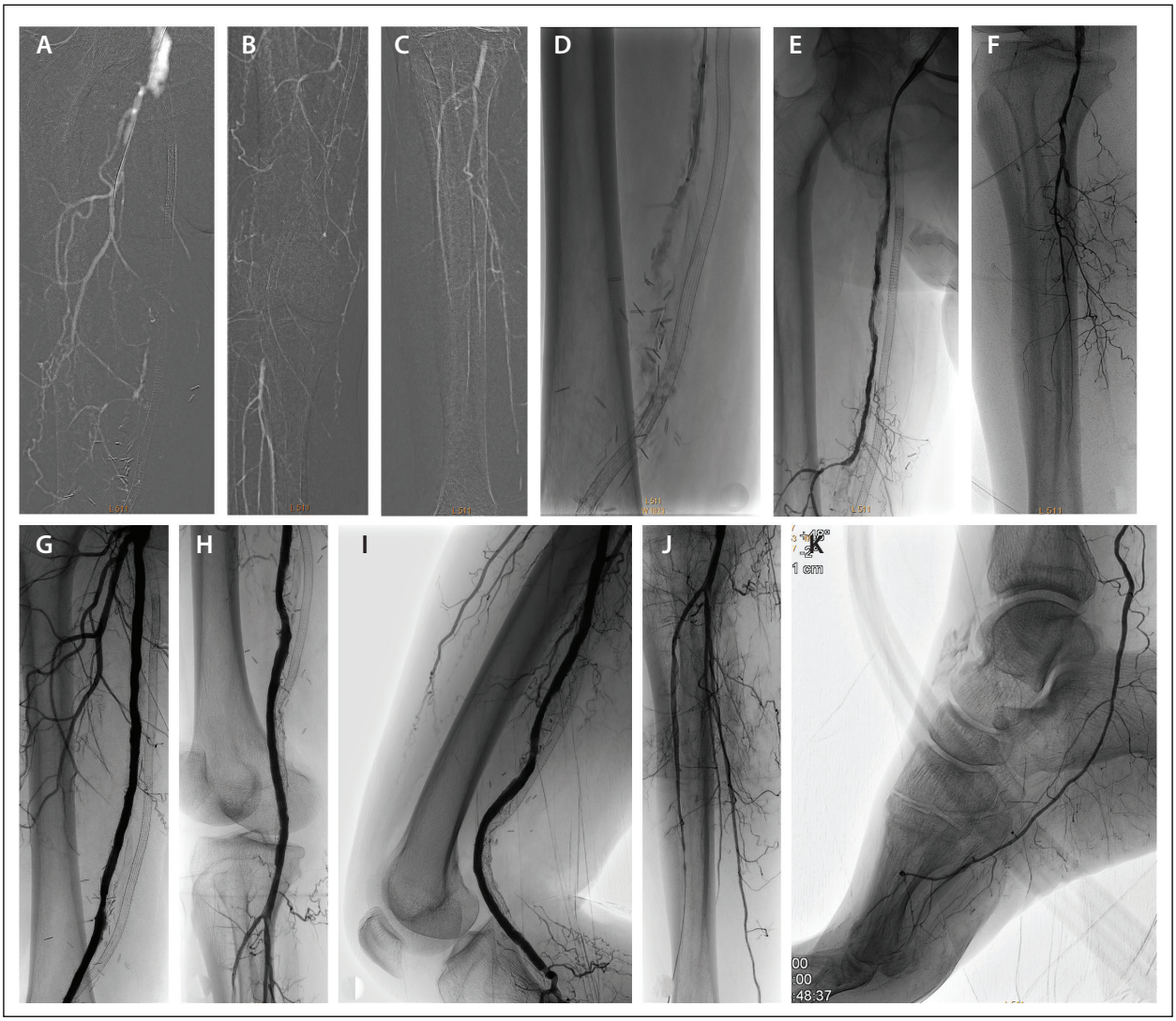

Figure 1. A 67-year-old patient with diabetes and CLI previously underwent a surgical bypass, which was followed 2 years later by an acute thrombosis of the bypass and implantation of a covered stent into the bypass using an endovascular approach, followed by acute thrombosis 4 days postprocedure. Attempted endovascular approach of the native SFA failed and resulted in an arterial rupture and surgical ligation. An antegrade CO_2 angiogram showed a long, calcified occlusion of the sutured SFA and popliteal artery, occlusion of the bypass, and very poor runoff, without identifiable flow for the foot (A–C). Antegrade, subintimal recanalization combined with retrograde access in the proximal anterior tibial artery supported a successful crossing (D–F). After adequate balloon angioplasty, treatment was completed with the implantation of three Supera stents (Abbott Vascular; combined antegrade and retrograde Supera implantation [PRESTO technique]). There was restoration of blood flow in the SFA-popliteal segments, with direct blood flow for the tibial and foot arteries (G–K).

attempt to cross an occlusion. It would be valuable to have adequate documentation that shows which hospitals and physicians have experience with the endovascular approach.

The availability of dedicated devices is also an important and determining factor when choosing a treatment approach. The considerable industry effort to create new instruments (ie, dedicated guidewires, support catheters, high-pressure and noncompliant balloons, DCBs, atherotomes, mimetic stents, DESs, and covered stents) means that the endovascular approach can be proposed more often in extreme situations and ensures a better long-term patency of the treated vessels. Every center that intends to hospitalize and treat patients affected by complex SFA lesions should be able to offer their patients the best treatment therapy available. The

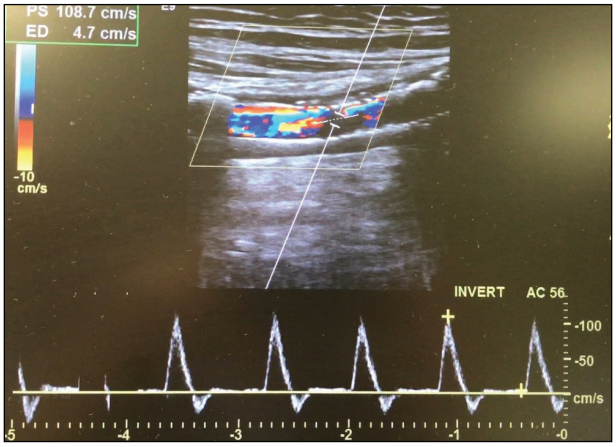

Figure 2. Follow-up duplex ultrasound of primary patency at 6 months.

success rate and patency are also directly related to the availability of those devices.

IMPACT OF THE REIMBURSEMENT SYSTEM

The role of the reimbursement system also impacts the capabilities and results of treatment of complex SFA CTOs. Every country in Europe has a different reimbursement system with unique budgets and number of patient procedures reimbursed between public and private health care hospitals.

Some countries have a device-based reimbursement system, with a general reimbursement for the endovascular procedure as well as an "extra reimbursement" for each specific device (ie, stents, DCBs, atherectomy). Device-based reimbursement systems are much more economical compared with a procedure-based reimbursement system, where each device used during the procedure is covered by a fixed reimbursement rate, without considering the specific expenses for each procedure done. Procedure-based reimbursement does not allow physicians to always offer every patient the best treatment.

A clear definition of complex SFA disease may help define the specific incremental costs with respect to a standard SFA lesion, allowing for the use of dedicated devices to become affordable without changing the whole reimbursement system.

ROLE OF EDUCATIONAL PROGRAMS

Educational programs have and will continue to have an important role in the development, evolution, and skills acquisition of new strategies for the treatment of complex SFA CTOs. Endovascular treatment of PAD is not well studied or developed among the vascular/endovascular specialists in training. To address this, many companies organize multiple courses on-site and abroad on endovascular treatment of complex SFA CTOs.

The most common issues among vascular specialists who approach these lesion types for the first time are a lack of advanced technical skills, along with inexperience using a subintimal approach, reentry strategies, and retrograde access. These skills are difficult to acquire during on-site observational training. The skill set for complex lesions needs specific and long-term training for both referral and high-volume centers. At our institution, we are establishing a fellowship program to offer physicians in training the best opportunity to learn and become confident with the most advanced and complex techniques.

DISCUSSION

PAD affects a significant number of patients around the world, creating disabilities and increasing patients' risk for amputation and death. Among the modern Western population, the risk factors that contribute to an increased risk of PAD continue to grow.

Many vascular/endovascular specialists are involved in the treatment of PAD, but there is no clear consensus regarding lesion classification and treatment indications. The TASC recommendations provide indications for an endovascular approach or surgical approach in an anatomic-oriented model rather than in a patient-oriented model. TASC C and D lesions should be treated by surgical revascularization, but many patients may not be good candidates for surgery because they are older, have multiple comorbidities, and/or have complex vascular lesions. These patients may benefit from an endovascular approach (Figures 1 and 2).[5] The PARC consensus proposes lesion classification that allows physicians to more easily understand lesion complexity.

When facing a complex SFA CTO, an evaluation of the best vascular therapy available to treat the patient should be completed. The German and Italian guidelines state that an endovascular approach is appropriate in most instances of PAD. However, if deciding between surgical and endovascular approaches, the guidelines also note that the approach should be selected based on the center's expertise and the physicians' skills.[13,14]

There is no specific list outlining which skills physicians must have before approaching a complex SFA CTO, about training requirements necessary to perform SFA interventions, or the minimum operator volume and outcomes required for complex SFA interventions. Many patients benefit, and many others could benefit, from adequate complex SFA CTO treatment, both with open repair or using an endovascular approach. Establishing a European training program that formally helps physicians in training acquire the advanced skills and demands a quality

control system may improve results of complex SFA CTO therapy.

An updated international registry of endovascular treatment for complex SFA lesions could be created in collaboration with the European societies of vascular specialists and the reference training centers in Europe. Specific criteria, such as the number of patients treated per year, the proportion of complex SFA treatments performed and the follow-up of those treatments (ie, minimum success rate, complication rates, procedure time reduction, reduction in device usage), freedom from reinterventions, and freedom from new clinical manifestations, must be better defined. Such a training of program would establish the necessary outcome centers needed to obtain and maintain certification as a "reference center for complex vascular lesion treatment" in Europe.

A training program would support development of expertise in treating complex lesions, help avoid attempting risky complex SFA CTO treatment that would lead to failure, prevent or reduce risks and complications, and lead to better treatment for patients. This program would also contribute to a better understanding of these complex diseases and procedures, as well as help collect data, develop new strategies, improve research, and support the evolution of dedicated devices.

Adoption of reference centers would enable treatment of complex diseases to be localized in experienced centers, increasing the volume and the number of procedures while also increasing the physicians' skills. These reference centers would offer physicians more opportunities to be confident with advanced technical strategies and devices. The centers will also enable physicians to have better access to the high-cost devices, increasing the success rate and the long-term outcomes in terms of patency and clinical success, reducing failure, and complication rates.

A review of the reimbursement system should be undertaken, with a focus of shifting to a device-based reimbursement system or developing new systems that consider the specific costs of complex procedures and seek the best treatment for every patient in Europe.

CONCLUSION

Due to the worldwide progression of diabetes mellitus and PAD, a huge number of patients affected by complex SFA popliteal lesions is expected in the future. The proper and correct clinical and interventional management of these patients will be needed to achieve the best clinical outcome.

A common European training program could help the scientific community create the PAD/CLI culture to achieve a homogeneous improvement in the physicians' skills and strategy choice. We strongly believe that only this type of program could create a real improvement in the knowledge, follow-up, and evaluation of the best treatment for PAD. This information could lead to an optimized and balanced European reimbursement system closer to the real-world procedure. ■

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