Applying Atherectomy in CLI Patients

A review of atherectomy modalities for treating critical limb ischemia and a look at the remaining challenges to overcome.

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Critical limb ischemia (CLI) is the most advanced manifestation of peripheral arterial disease and is characterized by persistently recurring rest pain requiring regular analgesia and/or nonhealing ulceration or gangrene of the foot or toes due to impaired blood flow to such an extent that the nutritive requirements of the tissues cannot be met. CLI is generally characterized by multilevel arterial occlusive disease or extensive below-the-knee (BTK) artery involvement and is associated with a high risk for limb and/or tissue loss.[1-3]

Early interventional percutaneous transluminal angioplasty studies reported limb salvage rates of 80% to 90% for CLI.[4-6] After a failed revascularization attempt, 40% to 50% of patients will lose their limb within 6 months and have mortality rates of up to 20%.[1] Scandinavian studies suggest that the increased availability and use of endovascular and surgical reconstructions have resulted in a significant decrease in amputations for patients with CLI. As shown in the BASIL trial,[7] percutaneous revascularization is as effective as surgical reconstruction in terms of limb salvage. For some CLI patients with severe comorbidities or a very limited chance of successful revascularization, a primary amputation may still be the most appropriate treatment.

After revascularization, ulcer healing may require adjunctive treatment, which may be best achieved in collaboration with the vascular specialist, diabetologist, and foot care specialists. Specialized local wound care and foot salvage procedures must be considered for limb salvage and to limit any tissue loss.[1,2]

Established techniques for the treatment of patients with multilevel occlusive disease are plain old balloon angioplasty (POBA) and stent implantation. For femoropopliteal lesions, the use of nitinol stents, paclitaxel-eluting stents, and drug-eluting balloons (DEBs)—where available—has been established based on recent controlled trials[8-14] and should be considered the standard of care. For BTK artery disease, POBA is still considered the method of choice. Early angioplasty series demonstrate limb salvage rates of up to 91% for surviving patients after 5 years in those who have been treated successfully.[1,2,5,6] With the use of POBA, the acute success of endovascular therapy in CLI patients and the durability in BTK lesions are limited.[1,2,4-7,15] It is noteworthy that temporary restoration of blood flow leads to pain relief and wound healing in simple ulcerations; however, in patients with infected and complex wounds requiring extensive wound care, long-term durability of sufficient blood supply to the foot is crucial and cannot be established in the majority of the cases using POBA without further reintervention.[16] Recent drug-eluting stent (DES) and DEB trials have shown significant improvements in vessel patency, and, in one, a decreased long-term amputation risk.[17-22]

CLI ATHERECTOMY TO DATE

The rationale for using debulking devices in a standalone procedure or as an adjunct for plaque modulation before POBA or stent implantation is in avoiding the potential drawbacks of angioplasty-induced barotrauma

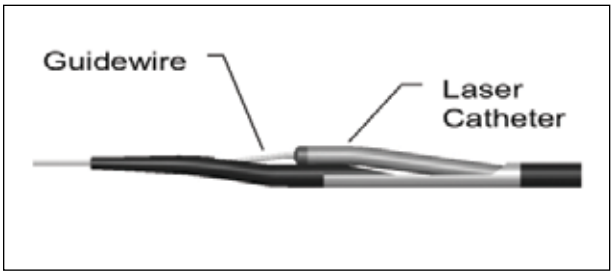

Figure 1. The Turbo-Tandem photoablation catheter.

such as dissection and acute recoil, as well as overwhelming neointima proliferation. Also, early failure of POBA might jeopardize the success of an initially successful endovascular procedure in CLI patients.

Excimer Laser-Assisted Angioplasty

The LACI trial[23] was the first controlled trial investigating the impact of using a debulking tool to facilitate angioplasty in CLI patients. In this international multicenter prospective single-arm trial, including 145 patients with 155 threatened limbs, a mean of 2.4 lesions were treated per intervention. The primary study endpoint was the 6-month limb salvage rate among survivors, which was achieved in 92% of surviving patients (or 93% of limbs). This study was performed using the earliest iteration of excimer laser catheters and only treated vessel diameters ranging from 0.9 to 2.5 mm, which resulted in a low standalone photoablation rate of 4%; lesion lengths and peak systolic velocity ratios were not reported in the outcomes. Since the availability of newer Turbo-Booster and Turbo-Tandem technologies (Spectranetics Corporation, Colorado Springs, CO), the efficacy of plaque reduction has significantly improved (Figure 1).[24,25] In the CELLO trial,[25] core lab adjudicated average absolute plaque reduction was 35% after Turbo-Booster passage.

Directional Atherectomy

The SilverHawk (Figure 2) and TurboHawk catheters (Figure 3) (Covidien, Mansfield, MA) are the most frequently used atherectomy devices worldwide. A US registry including 69 CLI patients demonstrated the efficacy of directional atherectomy in avoiding unplanned major amputation.[26] At 6-month follow-up, no unplanned major amputation was observed, with a low target lesion revascularization rate of 4%. McKinsey et al found a 1-year limb salvage rate of 84% in their CLI cohort.[27]

The recently presented data from the DEFINITIVE LE study[28] included 201 of an overall 800 patients who were suffering from CLI Rutherford class 4 (37%), 5 (53%), and 6 (10%). The primary endpoint of this study subcohort was 1-year freedom from unplanned major amputation, which was reached in 95%. Complete wound healing was observed in Rutherford classes 5 and 6 in 52%, 61%, and 72% after 3, 6, and 12 months, respectively. Primary and secondary 1-year vessel patencies were 71% and 88%, respectively (infrapopliteal lesion length of 6 cm). The improved complete wound healing rates during follow-up underlines the importance of long-term vessel patency. The primary patency rates in DEFINITIVE LE had not been seen before in this anatomic territory with these lesion lengths in previous trials.

Rotational Aspiration Atherectomy

The Jetstream atherectomy system (Bayer, Indianola, PA) is a rotating, aspirating catheter with tip sizes of 1.6 and 1.8 mm for tibial arteries, and an expandable catheter with a tip size ranging from 2.1 to 3.4 mm for active removal of atherosclerotic debris and thrombus from the peripheral vasculature (Figure 4). Currently, the only published results are limited to patients with claudication.[29] The introduction of a smaller device dedicated to tibial arteries might increase the use of this technology in CLI patients, but to date, we have little to no data to describe its benefit in these types of patients.

High-Speed Rotational Atherectomy

Highly calcified atherosclerotic plaque has created the need for the development of high-speed rotational

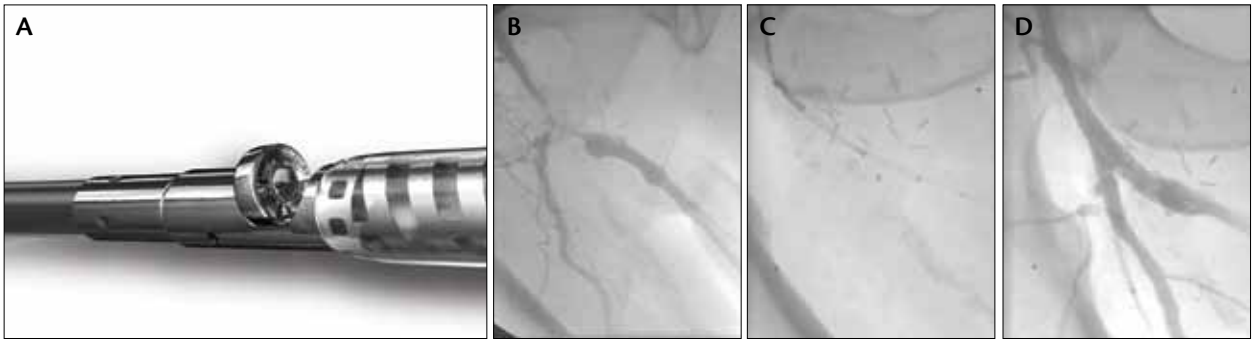

Figure 2. The SilverHawk directional atherectomy catheter (A). Common femoral bifurcation stenosis including a venous femoropopliteal bypass anastomosis (B); SilverHawk atherectomy (C); final result (D).

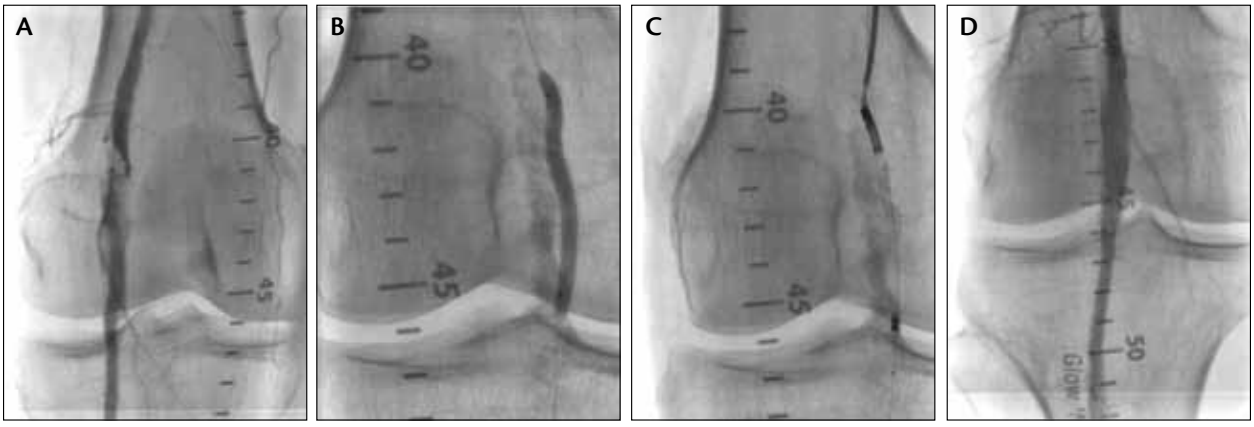

Figure 3. Subtotal calcified occlusion of popliteal artery (A); predilatation with a 3-mm balloon (B); TurboHawk atherectomy (C); final result after directional atherectomy and 6-mm balloon angioplasty (D).

devices aimed specifically at lesions where POBA has been shown to be suboptimal. The Rotablator system (Boston Scientific Corporation, Natick, MA) represents one of the technologies that utilize calcium ablation to achieve larger lumens. The Rotablator has been used for over 20 years to treat challenging, calcific coronary artery disease. The diamond-coated burr is designed to preferentially engage calcium and modify lesion compliance. This technology has traditionally been reserved for dedicated indications such as POBA-resistant BTK lesions. Therefore, no larger series on Rotablator use in CLI patients exist.

Orbital Atherectomy

The Diamondback 360° orbital atherectomy device (Cardiovascular Systems, Inc., St. Paul, MN) represents a new advancement in technology,[30] featuring a drive shaft with an eccentrically mounted, diamond-coated crown (Figure 5). The eccentric position of the crown creates an orbital spin. As the speed of the crown increases from centrifugal force, it sands wider spaces, thereby providing variability in its working range.[30] In a small randomized trial including 50 CLI patients treated either with POBA or orbital atherectomy plus POBA, Shammas et al[31] found an association between lumen gain with a residual stenosis > 30% and the risk of serious adverse events (revascularization, amputation, or death) during follow-up. There was a statistically significant decrease in major adverse events with orbital atherectomy plus POBA versus POBA alone, and additionally, lower inflation pressures after orbital atherectomy were noted.

THE POTENTIAL FUTURE ROLES OF ATHERECTOMY

The future role of atherectomy in general (not only limited to CLI patients) depends on the accessibility and costs of competitive technologies such as DES and DEB. This could result in different scenarios playing out between the United States and other markets. To prevent limb loss, which is the major goal of endovascular therapy for CLI patients, acute treatment success is essential for immediate pain relief and wound healing of focal simple skin ulcerations. This acute treatment success can be achieved with almost all technologies, even with simple POBA and provisional stenting. In the acute and short-term follow-up phase, the key advantage of atherectomy is in avoiding stent placement in bifurcation lesions and vessel areas with a high likelihood of developing in-stent restenosis. Moreover, atherectomy results in improved acute lumen gain, which seems to be predictive for reduced lesion-related events during follow-up.[31,32]

Figure 4. Extended tip of the Jetstream rotational aspiration atherectomy catheter.

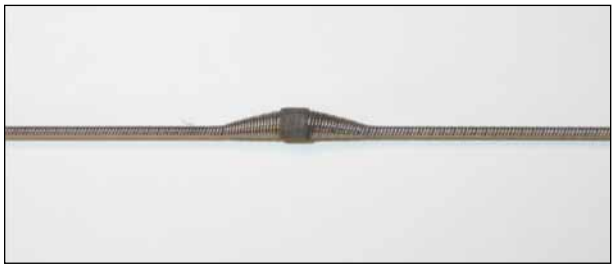

Figure 5. The Diamondback classic crown high-speed orbital atherectomy catheter.

In the longer term, according to the DEFINITIVE LE results, directional atherectomy has achieved acceptable patency results across all infrainguinal vessel areas, including tibial arteries, which are in the treatment range of DES and DEB. Durability of the procedure might be further improved when combining atherectomy with DEB angioplasty, a strategy that is currently being investigated in the DEFINITIVE AR study. It is well known that interrupted blood flow to the foot results in deterioration of tissue healing in complex wounds—even if vessel patency is restored by a reintervention. A recent trial has shown a significant reduction in the 2-year amputation rate, favoring patients with BTK disease who were treated with DES as compared to bare-metal stents.[17,18] DEBs are major competitors to atherectomy in the treatment of diffuse BTK artery disease; in more focal lesions, DES will compete as well. As both technologies are not approved in the United States for BTK applications, atherectomy will play a major role in the treatment of this particular patient cohort, whereas out of the United States, both drug-eluting techniques will have preference due to their ease of use—as long as adequate reimbursement is established.

CONCLUSION

In summary, using dedicated devices and appropriate techniques, the majority of CLI patients can experience improved blood supply to the foot with an endovascular approach, collectively leading to limb and tissue salvage. A toolbox of different devices must be available—no device fits all pathologies. The future challenge is improving the durability of the procedures and knowing which device is optimal in which patient. Atherectomy followed by local drug delivery will play a key role in achieving improved durability.

One of the remaining challenges for all trials and the applicability to our patients is the ability to compare devices between trials, which remains difficult because of the heterogeneity of the patients treated in each trial, lesion lengths, and ultimately, the metric used for primary patency. Ultimately, having direct comparative trials will be an integral part of the scientific data landscape that we as operators will require to determine the best therapy and device for optimal durability for limb/tissue salvage. ■

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