Advances in Peripheral Arterial Disease Endovascular Revascularization

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KEYWORDS

• Peripheral arterial disease • Chronic total occlusion • Atherectomy • Complication • Outcome

KEY POINTS

- Peripheral arterial disease (PAD) has increasingly become a worldwide problem; in the United States PAD affects 8-12 million Americans.
- Significant advances have been made in the endovascular treatment of lower extremity arterial occlusive disease.
- Since the last update in 2011, new technologies have been developed, predominantly in reentry devices and treatment of chronic total occlusion lesions.

HISTORY OF PERIPHERAL ARTERIAL DISEASE INTERVENTION

Peripheral arterial disease (PAD) has increasingly become a worldwide problem; in the United States, PAD has a prevalence of 12% in the general population, affecting 8-12 million Americans.[1,2] The prevalence of PAD increases with age and is as high as 20% in Americans older than 65, affecting as many as 7.6 million people (prevalence becomes exponentially higher with the presence additional risk factors for vascular disease).[1,2] PAD of the lower extremities encompasses a wide clinical spectrum that ranges from asymptomatic disease to critical limb ischemia. Left untreated, advanced PAD can lead to significant morbidity,[2] and is the most common cause of lower extremity amputation when not revascularized.[3] Limb preservation can lead to significantly decreased mortality (2-year mortality in patients undergoing amputation is nearly 40%[3]). Over the last decade, the number of endovascular procedures for critical limb ischemia has increased by nearly 4-fold, which has coincided with a significant decrease in amputation rates.[4]

Lower extremity PAD presents unique clinical and therapeutic challenges. The management of lower extremity PAD can be extremely difficult given the diffuse atherosclerotic burden, chronic total occlusion (CTO), presence of critical limb ischemia, and lack of quality distal run-off. These unique features limit the success of traditional, angioplasty-based (endovascular) therapies/interventions and contribute to the disappointing results observed with balloon angioplasty for management of these complex lesions.[5] These clinical and technical challenges have led to the development of a myriad of new technologies aimed to enhance the safety and improve the effectiveness of percutaneous revascularization strategies in the management of PAD.

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This review builds on the recent advances in the endovascular management of PAD as discussed in 2011.[6] Therefore, for relevancy, it focuses on the technologies related to atherectomy, advances in nitinol self-expanding balloon stents, and advances in device technology for the treatment of CTO. Available drug-eluting technologies are reviewed elsewhere in this issue of *Cardiology Clinics*. For other interventions, please refer to the 2011 update.[6]

ADVANCES IN PLAQUE REMOVAL AND DEBULKING

Atherectomy

Excimer laser

Early attempts at laser-based endovascular devices used continuous-wave, heat-tipped laser technology. These early attempts were quickly abandoned in the late 1980s owing to high complication rates from thermal damage to the surrounding vascular tissues, leading to high restenosis rates.[7] The advent of the excimer laser-assisted system (Spectranetics Corporation, Colorado Springs, CO) allowed for the use of flexible fiberoptic catheters capable of directing ultraviolet light to penetrate into the fibrous cap/plaque. The 308-nm laser a has short penetration depth of 50 μm, which allows for direct ablation of the plaque on contact alone, without a subsequent rise in surrounding temperature delivered to the surrounding tissue. These catheters showed promising initial success rates of 90.5% with primary and secondary patency rates of 33% and 75.9%, respectively, as reported by Scheinert and colleagues.[8] These results were echoed in the Peripheral Excimer Laser Angioplasty (PELA) Trial with primary patency rates determined by ultrasound of 48% in the laser arm and 58% in the angioplasty arm.[9]

The design of the TURBO-Booster catheter (Spectranetics Corporation) aimed to create a channel larger than the diameter of the catheter itself, utilizing a custom guide catheter that allowed for the laser to directionally ablate tissue, thus creating a larger lumen. Utilizing these catheters, the Clirpath Excimer Laser System to Enlarge Lumen Openings (CELLO) study demonstrated patency rates (percent stenosis <50%) of 59% and 54% at 6 and 12 months, respectively, with target lesion revascularization (TLR) required in 23.1% of study participants.[10]

Excisional and orbital atherectomy

Since the 2011 update,[6] there have been only a few significant trials comparing directional atherectomy devices to primary balloon angioplasty (PBA). In a prospective, 2-center, randomized trial, the SilverHawk atherectomy catheter (Covidien, Plymouth, CO) with adjunctive PBA was compared with PBA alone for treatment of infrainguinal disease.[11] Fifty-eight patients were randomized (36 vessels in the atherectomy arm and 48 vessels in PBA arm) and followed for the primary endpoint of TLR at 1 year, secondary outcomes rate of "bailout" stent placement, and the rate of target vessel revascularization. Results of the study showed no difference in TLR at 1 year (16.7% vs 11.1%) or target vessel revascularization (21.4% vs 11.1%). There was, however, a significant difference in the need for bailout stent placement (27.6% in the atherectomy arm vs 62.1% in the PBA arm; $P = .017$).

Major adverse outcomes were similar between groups; however, there was a significant difference in distal microembolization (64.7% [n = 17] vs 0% [n = 10]) when an embolic filter was used.[11] The prospective, multicenter, single-arm DEFINITIVE Ca^{++} study aimed at evaluating the effectiveness and safety of the SilverHawk and TurboHawk (Covidien, Plymouth, CO) catheters when used with a distal embolic protection device.[12] The 30-day freedom from major adverse events was 93.1%, with a primary effectiveness endpoint ($\leq$50% residual diameter stenosis) of 92%. Technical success showed a residual diameter stenosis of 33.3% (further reduced to 24.1% with adjunctive therapy). The clinical improvement to asymptomatic status (Rutherford–Becker Class = 0) at 30 days increased from 0% to 52.3%; 88.5% of patients experienced a symptomatic improvement of at least 1 Rutherford–Becker Class categories.

Jetstream

Jetstream systems (Bayer Health System, Leverkusen, Germany) offer both expandable and single-cutter options. The expandable system achieves graded atherectomy using 2 sets of rotating stainless steel blades. The first set of blades sits within a fenestrated metal housing situated at the tip of the catheter, which allows cutting in a diameter just over 3 mm when rotated clockwise. The second set of 5 blades are hinged and mounted just proximal from the distal housing, also allowing for cutting to a diameter of 3 mm when rotated counterclockwise. The single-cutter catheter system has a longer working shaft, which allows for it to be utilized for the revascularization of more distal lesions and is available in sizes ranging from 1.6 to 1.85 mm. Both systems work via differential cutting, which allows for fibrous and calcified tissue/plaque to be preferentially cut sparing the normal more compliant tissue.