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STRUCTURAL HEART

Management of Complex Valve Disease Patients

CLD talks with Structural Cardiologist Lowie Van Assche, MD, Baptist Health South Florida, Miami, Florida, about his presentation at Baptist Health's Echocardiography and Structural Heart Symposium, which took place September 27th-28th in Coral Gables, Florida.

How are standard structural heart disease patients different from more complex patients?

For most of our transcatheter aortic valve replacement (TAVR) or transcatheter edge-to-edge repair (TEER) population, the heart team approach has become straightforward. Usually these are stable outpatients, and we discuss each patient as a team in an effort to decide if we should provide medical management, transcatheter therapy, or surgical therapy. However, not infrequently, we will encounter patients who are very sick and it is unclear as to what approach we should take. These patients have complex presentations, fall outside of the guidelines, and don't fit inside the usual pathway of how we treat patients. The good news is that with new transcatheter therapies, we can help some of these patients who are not necessarily within what we might consider standard of care practice. In patients who have acute complications, the number one thing we try to do is get them out of trouble. If we can prevent these patients from decompensating and dying, many will go on have a positive outcome.

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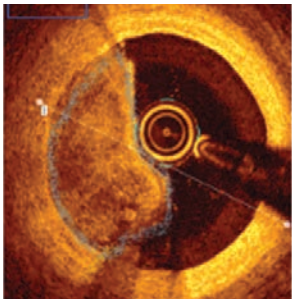
CLINICAL IMAGES

Optical Coherence Tomography in the Peripheral Vasculature



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Retrospective Review of Directional Atherectomy and Drug-Coated Balloon Use in a PAD Safety-Net Population

Shea E. Hogan, MD, MSCS; Matthew Holland, MD; Joseph Burke, MD; Paisley Johnson, MD; Demetria McNeal, MD; Lisa Cicutto, MD; Mark Nehler, MD; Pamela N. Peterson, MD, MSPH

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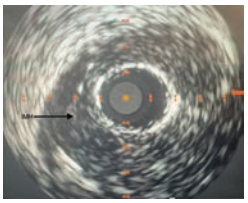
CASE REPORT

Not the Usual Suspect: Intracoronary Hematoma Presenting as an Acute STEMI



Yashwant Agrawal, MD; Dominika M. Zoltowska, MD; Anthony Elghoul; Anwita Reddy Nimma; Tim A. Fischell, MD

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HMP Global

Retrospective Review of Directional Atherectomy and Drug-Coated Balloon Use in a PAD Safety-Net Population

Shea E. Hogan, MD, MSCS; Matthew Holland, MD; Joseph Burke, MD; Paisley Johnson, MD; Demetria McNeal, MD; Lisa Cicutto, MD; Mark Nehler, MD; Pamela N. Peterson, MD, MSPH

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Peripheral artery disease (PAD) is a common condition affecting millions of Americans and is associated with functional impairment, morbidity, and mortality.[1] While aggressive risk-factor modification and medical management are the mainstays of treatment,[1] lower-extremity revascularization via a surgical or percutaneous approach improves function and decreases the risk of leg amputation in those with limb threat due to critical limb-threatening ischemia (CLTI), the most severe stage of PAD.[2] Minorities and patients who are under- and uninsured are at particular risk, as they are more likely to present with CLTI, are less likely to undergo lower-extremity revascularization for limb salvage, and are more likely to have limb amputation.[3-5]

Numerous devices are used during percutaneous lower-extremity revascularization, including balloons, stents, drug-coated technology, intravascular lithotripsy, and atherectomy.[2] However, for the femoropopliteal arteries (superficial femoral and popliteal arteries), a gold-standard treatment algorithm has yet to be determined,[6] particularly for long and complex disease.[7,8] Thus, the standard of care for many years has been balloon angioplasty and provisional stenting for flow-limiting dissections. While stenting for flow-limiting dissections improves short-term vessel patency, it is associated with high rates of in-stent restenosis and need for subsequent intervention.[9-10] Newer, drug (paxclitaxel)-coated balloon (DCB) technology use has resulted in better short- and long-term patency in this segment, making a "leave nothing behind" approach possible.[11,12] Due to concerns about drug update in heavily calcified vessels, atherectomy is often used to modify plaque and thus increase drug uptake by the vessel wall, as well as decrease the need for stenting.[11] To date, only 2 small randomized, controlled trials have specifically looked at directional atherectomy plus DCB. Furthermore, the vast majority of patients had less severe disease — presenting with claudication and not CLTI.[13,14] Therefore, the objective of this study was to examine patient characteristics, short- and intermediate-term efficacy, and safety of directional atherectomy plus DCB during lower-extremity revascularization in a safety-net population.

Methods

Institutional EPIC records were reviewed by SEH, from April 12, 2016 until January 1, 2020. Patients were identified by reviewing the cardiac catheterization schedule (where all procedures occurred) for each day within this timeframe. Charts were reviewed for patients who underwent any type of peripheral procedure. Those who underwent directional atherectomy plus DCB were included, and demographic, medical, anatomic, and outcome data were collected.

Femoropopliteal anatomy was classified using the Trans-Atlantic Inter-Society Consensus Document on the Management of Peripheral Arterial Disease II guidelines.[15] Anatomy was classified as Type A, B, C, or D based on the number and length of lesions, the presence and location of chronic total occlusions, and the presence of heavy calcification. Type A disease is the least severe and the most likely to be successfully treated with percutaneous lower-extremity revascularization, whereas Type D is the most severe and the least likely to be treated successfully with percutaneous lower-extremity revascularization.

For patients presenting with lower-extremity wounds, the Wound, Ischemia, foot Infection (WIfI) scoring system was used, which takes into account the presence, location, and extent of the wound, the presence of ischemia based on noninvasive pressure testing (ankle-brachial index [ABI] and/or toe pressure), and the presence of wound infection. WIfI scores were determined using the Society of Vascular Surgery (SVC) calculator.[16]

Ethical approval for this research was obtained from Denver Health's institutional review board, SPARO, and from the University of Colorado institutional review board, COMIRB. All information was compiled in REDCap and statistical analyses were performed using REDCap and Excel.

Results

Between April 12, 2016 and January 1, 2020, a total of 58 patients underwent percutaneous lower-extremity revascularization including both directional atherectomy and DCB treatment. The median patient age at the time of index lower-extremity revascularization was 66 years, 41% were female, 72% were white, 31% were Hispanic, and 24% were Black/African American (Table 1). Seventeen percent of patients spoke a non-English primary language, and 10% reported current or previous housing insecurity. The majority had diabetes mellitus, hypertension, a history of tobacco use, and dyslipidemia (Table 1). Furthermore, most patients (58%) had undergone previous lower-extremity revascularization of the index leg (of which 61% had previous lower-extremity revascularization of an index vessel), and 19% had undergone a previous minor amputation of the index leg. At the time of presentation to a vascular medicine provider, most patients were on antiplatelet and statin therapies (Table 1).

All patients underwent lower-extremity revascularization at Denver Health Hospital in Denver, Colorado. All procedures were performed by 1 of 3 interventional cardiologists employed by Denver Health (SEH, MH, JB). The decision to use directional atherectomy plus DCB was at the discretion of each operator

TABLE 1. Baseline patient characteristics, risk factors, and medications at the time of first vascular provider encounter.

	Patients (n = 58)
Age (years)	66 (60-72)
Female	24 (41%)
Race	
White	42 (72%)
Black/African American	14 (24%)
Asian	1 (1.7%)
Native Hawaiian/Other Pacific Islander	1 (1.7%)
Ethnicity	
Not Hispanic/Latino	40 (69%)
Hispanic/Latino	18 (31%)
Preferred language	
English	48 (83%)
Spanish	9 (15%)
Russian	1 (2%)
Housing insecurity	
None	52 (90%)
Currently	4 (7%)
History of	2 (3%)
Diabetes mellitus	45 (78%)
Hypertension	51 (88%)
Any history of tobacco use	45 (78%)
Current tobacco use	26 (58%)
Previous tobacco use	19 (42%)
Current marijuana use	5 (9%)
Unknown marijuana use	14 (24%)
Dyslipidemia	33 (57%)
Corona disease	21 (36%)
History of coronary revascularization	16 (76%)
Cerebrovascular disease	11 (19%)
Chronic kidney disease	12 (21%)
Previous peripheral vascular intervention	31 (53%)
On index leg	18 (58%)
On index leg, index vessel	11 (61%)
Heart failure	19 (33%)
Heart failure with reduced EF	12 (63%)
Heart failure with preserved EF	7 (37%)
Atrial fibrillation	9 (16%)
Previous lower extremity amputation index leg	11 (19%)
Aspirin	41 (71%)
Clopidogrel	22 (38%)
Statin	52 (90%)
Anticoagulant	10 (17%)

Data presented as median (interquartile range) or number (%). EF = ejection fraction.

— no formal algorithm was utilized, although the goal of all 3 operators was to use this approach if "leave no stent behind" was possible based on patient anatomy. The directional atherectomy device used for all cases was the Medtronic HawkOne device. The DCB used for all cases was the Medtronic InPact Admiral DCB.

Clinical presentation. Sixty-five percent of patients presented with CLTI — roughly 10% with ischemic rest pain (Rutherford category 4), more than half with nonhealing minor foot wounds (Rutherford category 5), and 3.4% with extensive, nonhealing leg wounds (Rutherford category 6). The majority of those presenting with foot wounds were WIfI clinical stages 3 and 4. The median ABI was 0.80, toe-brachial index (TBI) was 0.35, and toe pressure was 45 mmHg (Table 2).

Anatomic disease in index leg. Seventy-nine percent of patients had obstructive disease involving the superficial femoral artery while 64% had disease in the popliteal artery; the majority also had obstructive infratibial disease (Table 2). The TASC fem-pop classification was fairly evenly distributed, although most patients had very complex disease (TASC D). Fifty percent of patients had a chronic total occlusion (CTO) that was intervened upon and 55% had calcified vessels (Table 2).

Percutaneous vascular intervention (PVI). Directional atherectomy was most commonly performed in the superficial femoral (74% of patients) and popliteal artery (60% of patients), although it was also utilized in the tibial arteries (42% of patients, most often in the tibial-peroneal trunk) (Table 3). The pattern of DCB use was similar — most treatment was performed in the superficial femoral and popliteal arteries (76% and 62%, respectively), but some use occurred in the infratibial arteries and

TABLE 2. Presenting clinical features and anatomic disease

	Patients (n = 58)
Presenting ankle-brachial index	0.80 (0.60-0.96)
Presenting toe-brachial index	0.35 (0.20-0.65)
Presenting toe pressure (mm Hg)	45 (26-68)
Presenting Rutherford category	
Category 2	8 (14%)
Category 3	12 (21%)
Category 4	5 (9%)
Category 5	31 (53%)
Category 6	2 (3%)
WIfI clinical stage	
Stage 1	3 (10%)
Stage 2	5 (16%)
Stage 3	9 (29%)
Stage 4	14 (45%)
Stage 5	0 (0%)
Anatomy, obstructive disease	
Iliac artery	1 (2%)
Common femoral artery	6 (10%)
Superficial femoral artery	46 (79%)
Popliteal artery	37 (64%)
Anterior tibial	33 (57%)
Tibioperoneal trunk	21 (36%)
Peroneal	28 (48%)
Posterior tibial	32 (55%)
Previous femoral-popliteal surgical graft	1 (2%)
TASC femoral-popliteal disease class	
TASC A	12 (23%)
TASC B	13 (25%)
TASC C	9 (17%)
TASC D	18 (35%)
Chronic total occlusion of intervened segment	29 (50%)
Calcification of intervened vessels	32 (55%)

Data presented as median (interquartile range) or number (%).

rarely in the iliac and common femoral arteries and once in a surgical bypass graft (Table 3).

Bailout stenting for flow-limiting dissection or vessel perforation was required in 9 patients (16%).

Procedural adverse events. Procedure-related adverse outcome rates were low (Figure 1). Four patients had a bleeding event (half of these were Thrombolysis in Myocardial infarction [TIMI] minor bleeding and half were TIMI minimal bleeding) and 1 had a vessel perforation requiring the placement of a covered stent. Seven patients (12%) had an embolic event down the tibial artery during directional atherectomy, but 6 of these were successfully treated with manual aspiration thrombectomy (the 7th required repeat intervention the following day).

Post-PVI course. The median follow-up was 128 weeks (interquartile range, 73-182). Following PVI, the median ABI increased to 1, the toe-brachial index to 0.7, and the toe pressure to 87 mmHg. Of patients with 1-month follow-up, most with presenting CLTI reported improved Rutherford category 1-3 symptoms. For those presenting with wounds, 2 in 3 experienced index wound healing (approximately 10% within the first month, 50% between 1-3 months, and 30% between 6-12 months).

At 2 years, 26% of patients required target vessel revascularization (TVR) (Figure 1); almost half of these events occurred within the first month after index PVI. Chronic (CLI) and acute limb ischemia (ALI) admissions for the index leg occurred in 17% and 9%, respectively, of patients during this timeframe. Minor vascular amputation occurred in 33% of patients and major vascular amputation was required in 14%. One patient with chronic renal insufficiency at baseline (stage 3B) developed contrast-induced nephropathy after requiring 2 back-to-back interventions (index intervention and then next-day intervention for vessel closure). He required temporary dialysis, but his kidney function eventually returned to baseline. Twenty-four percent of patients with data at 2 years had died (Figure 2).

Of Rutherford 5 patients presenting with nonhealing ischemic leg and foot wounds, 75% healed their wounds. Of those who healed, nearly all (>90%) healed within 12 months and >70% healed within 6 months. Not surprisingly, CLTI admissions (29%) and minor vascular amputations (52%) at 2 years were higher than those presenting with Rutherford 2-4 and the major amputation rate for this group (19%) was lower than in patients presenting with Rutherford 6 (100%).

Major vascular amputation. Eight patients required major vascular amputation of the index leg within 2 years of index PVI. Compared with the rest of the cohort, these patients were younger (median age, 60 years), were more likely to be male (75%), and were more likely to be diabetic (88%) and hypertensive (100%). Six of the 8 had noncompressible ABIs on presentation, and the median presenting toe pressure was 30 mmHg. All these patients were Rutherford category 5 and 6 on presentation, with WIfI stage 3 and 4 stage wounds. These

TABLE 3. Percutaneous lower-extremity revascularization methods.

	Patients (n = 58)
Vascular access	
Contralateral common femoral artery	47 (81%)
Antegrade common femoral artery	11 (19%)
Pedal	11 (19%)
Vessels atherectomy performed	
Common femoral	4 (7%)
Superficial femoral artery	43 (74%)
Popliteal artery	35 (60%)
Anterior tibial artery	6 (10%)
Tibioperoneal trunk	8 (14%)
Peroneal artery	5 (9%)
Posterior tibial artery	5 (9%)
Femoral-popliteal bypass graft	1 (2%)
Drug-coated balloon used	
Iliac artery	1 (2%)
Common femoral artery	4 (7%)
Superficial femoral artery	44 (76%)
Popliteal artery	36 (62%)
Anterior tibial artery	4 (5%)
Tibioperoneal trunk	7 (12%)
Peroneal artery	3 (5%)
Posterior tibial artery	3 (5%)
Femoral-popliteal bypass graft	1 (2%)

Data presented as median (interquartile range) or number (96).

patients had similar anatomy and intervention as the rest of the population included. Only 1 of the 6 experienced an improvement in Rutherford category (to category 3) 1 month after revascularization. Half of the patients required TVR, all within 6 months. CLI admission rates at 2 years were higher (75%, all within 6 months) but ALI rates were lower (no events). Nearly all major amputations (7 of 8) occurred within 6 months. Half of these patients died by 2 years.

TASC classification. Bailout stenting rates were low for the spectrum of disease severity, and (not surprisingly) TVR rates at 2 years increased with disease complexity (Figure 3).

Discussion

This retrospective, observational review of a symptomatic PAD population who underwent lower-extremity revascularization at a safety- net hospital between April 2016 to January 2020 demonstrated that directional atherectomy plus DCB use was associated with low bailout stent rates, low short-term TVR rates, low complication rates, and improved clinical outcomes. Furthermore, these outcomes were observed in the setting of late-stage disease in a historically underserved population. This study has 2 unique features: it examines the use of a specific endovascular technique in the treatment of PAD, and it also features an undertreated and high-risk population.

Directional atherectomy plus drug-coated balloon use. While many new devices and techniques have evolved over the past decade, a standard and durable treatment of complex femoropopliteal disease has not been established.[17] Atherectomy devices debulk and remove atherosclerotic plaque by cutting, pulverizing, and shaving.[8] A variety of atherectomy devices are available and use rotational, orbital, directional, excisional, and laser technologies.[18] Compared with percutaneous transluminal angioplasty and stent implantation, atherectomy offers the potential theoretical advantages of decreasing arterial wall stretch injury, decreasing dissection (and thus the need for stenting), and reducing recoil and subsequent restenosis.[8] The DEFINITIVE LE trial assessed directional atherectomy safety and effectiveness in patients with symptomatic PAD and demonstrated high vessel patency and freedom from unplanned target-limb amputation at 12 months with low rates of periprocedural adverse events. However, only 15% of the 799 patients enrolled presented with nonhealing ischemic ulcers.[19]

Other studies have shown mixed results with directional atherectomy use, although many of these trials enrolled a small number of patients[20,21] or had flawed designs.[22] The most recent Cochrane review of 7 studies (527 participants) examining the effectiveness of atherectomy during percutaneous intervention for PAD concluded that there is uncertain evidence that atherectomy improves vessel patency, mortality, and cardiovascular event rates compared with balloon angioplasty with or without stenting.[23] It is notable that the review included different atherectomy types and was not focused on directional atherectomy. Additionally, the review did not include

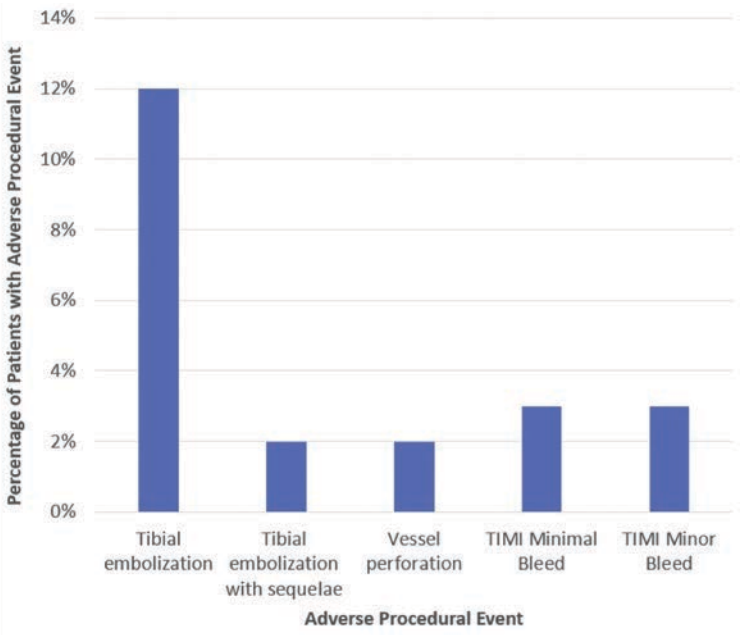

Figure 1. Short-term procedural adverse events.

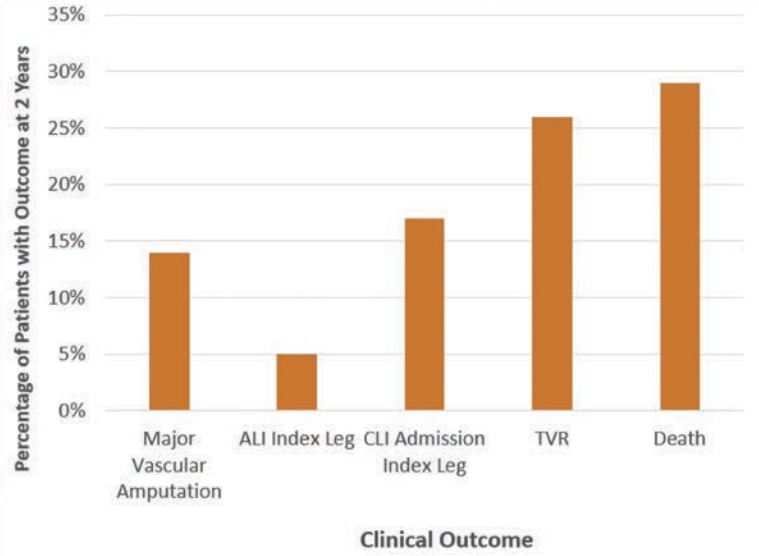

Figure 2. Two-year clinical outcomes after percutaneous vascular intervention.

ALI = acute limb ischemia; CLI = chronic limb ischemia; TVR = target-vessel revascularization.

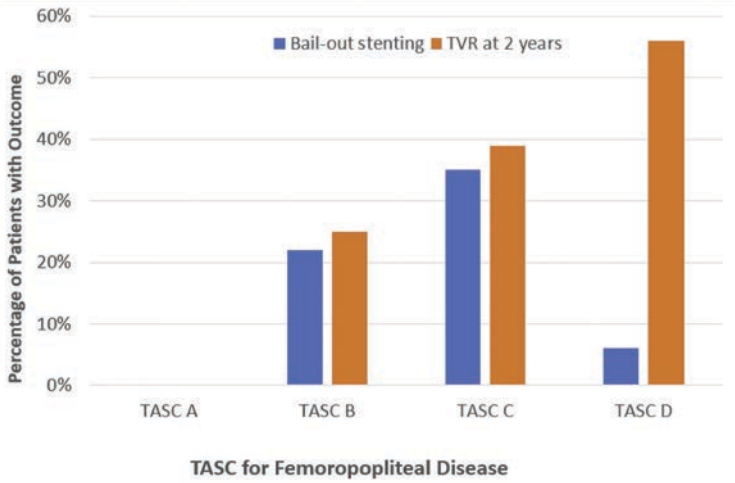

Figure 3. Bailout stenting during percutaneous lower-extremity revascularization and need for target-vessel revascularization 2 years after index procedure, stratified by presenting femoropopliteal TASC classification.

TVR = target-vessel revascularization.

treatment with DCB technology, which has been shown to improve patency compared with both balloon angioplasty and implantation of bare-metal stents.[24]

The use of combined atherectomy (most often directional and orbital) and DCB has been studied, and has been shown to improve vessel patency compared with non-coated balloon angioplasty.[25] A meta-analysis of 6 studies (2 randomized controlled trials and 4 retrospective cohort studies) including 470 patients found that atherectomy plus DCB resulted in lower incidence of bailout stenting compared with DCB alone.[11] In the DEFINITIVE AR trial, 102 patients were randomized to directional atherectomy plus DCB vs DCB alone. Directional atherectomy plus DCB was found to be safe and effective, but there was no difference in clinical TLR between groups (P=.90). It is notable that again the vast majority of patients presented with claudication, not CLTI.[13]

Safety-net population. In the Institute of Medicine's publication, "America's Health Care Safety Net: Intact but Endangered," safety net providers were defined by 2 characteristics: (1) access to care regardless of a person's ability to pay; and (2) a large proportion of uninsured, Medicaid, and/or vulnerable patients.[26] A prospective, multicenter PAD registry (the PORTRAIT study) showed that patients with financial barriers to medical care (defined as those who were uninsured as well as underinsured patients reporting financial concerns due to medical care) were more likely to have a delayed presentation (60% presented with symptoms lasting >1 year), were less likely to be compliant with prescribed medications and had worse health status (more functional limitations, more symptoms, lower social functioning, less treatment satisfaction, worse quality of life) at presentation and at 12 months.[3]

The population included in this analysis is unique, as the setting was Colorado's primary safety-net medical institution, which cares for one-third of Denver's population. As of 2022, this population is approximately 70% White, 13% Black, 4% Asian, and 35% Hispanic. Astonishingly, 74% of the hospital's population has no insurance coverage. Otherwise, 15% of the population is covered by Medicaid, 4% by commercial insurance, 2.5% by Medicare, and 4% by hospital-run assistance programs. While the majority speak English as their primary language, 16% speak Spanish and the remainder speak other languages (including Arabic, Vietnamese, Russian, Nepalese, Amharic, Somalese, Burmese, French, Chinese, Tigrinya, Dari, Sahili, Pashto,

and Korean). The population also includes prisoners — 2 of the 58 individuals in this analysis were currently or recently incarcerated — as well as individuals with current or previous housing insecurity (10%).

In addition to what is known about health care for safety-net populations, a substantial body of research has established the differential risk factor control, PAD diagnosis and management in United States (U.S.) minority populations.[27] An analysis of more than 2000 U.S. patients with symptomatic PAD in the REACH registry revealed that compared with non-Hispanic White patients, Black and Hispanic patients had worse blood pressure and lipid control, and were less likely to be on aspirin and statin therapy. Black patients were significantly less likely to undergo lower-extremity bypass surgery.[28] A devastating sequela of CLTI is major lower-extremity amputation. It has been more than 2 decades since the initial observations of higher lower-extremity amputation rates for PAD in Black and Hispanic populations,[29] and shockingly, this disparity continues to exist.[27] One review of inpatients from 1998 to 2002 showed that patients were more likely to undergo primary amputation for lower-extremity ischemia if they were non-White (odds ratio [OR], 1.91; 95% confidence interval [CI], 1.65-2.20), low income (OR, 1.41; 95% CI, 1.18-1.60), and covered by Medicare or Medicaid (OR, 1.81; 95% CI, 1.66-1.97).[5] Major leg amputation is associated with significant morbidity and mortality; of Medicare beneficiaries who underwent a lower-limb amputation for vascular disease in 1996, 26% required a subsequent amputation procedure within 12 months and over one-third died within 1 year of the index amputation. It is estimated that acute and postacute medical costs in caring for these patients exceeded $4.3 billion U.S. dollars.[30]

Given what is known about safety-net and minority PAD populations, it is not surprising that most of this cohort (53%) presented with Rutherford category 5 symptoms. However, the majority (three-quarters) of these patients went on to heal their wounds after revascularization, most within 6 months. While healing rates were similar to a cohort treated with surgical revascularization for CLI, our population did not experience the adverse events associated with surgery — incisional wound healing time, loss of ambulatory function, and loss of independent living status.[31] While many of the patients in this analysis underwent evaluation for surgical revascularization, including vein mapping, this information was not collected during chart abstraction.

Effective CLTI management, including successful and durable lower-extremity revascularization, is necessary to keep these patients out of the hospital and functioning at a high level. Because our patients present with more severe disease, are more likely to be lost to follow-up, and are at even higher risk for the destabilizing effects of leg amputation, our group strives to achieve the best lower-extremity revascularization result possible. Our multidisciplinary Limb Salvage Program, which includes a spectrum of disciplines (among them interventional cardiology, vascular surgery, vascular medicine, podiatry, infectious disease, primary care, geriatrics, physical medicine and rehabilitation), is essential to address many of the concurrent issues patients are facing. This analysis demonstrates that directional atherectomy and DCB during lower-extremity revascularization, in addition to good medical therapy and multidisciplinary care, are safe and associated with successful clinical outcomes in a high-risk and late-presenting population.

Strengths and limitations. A major strength of this study was the direct verification of directional atherectomy and DCB during a PVI by chart (not ICD code) review. Another strength is the time of observation (for some patients, >2 years).

There are several limitations to this study, the first of which is its observational design. Furthermore, the study was limited to a single center and included a small number of patients. Since a treatment algorithm was not utilized, treatment bias was likely present.

Conclusions

Directional atherectomy and drug-coated balloon use during endovascular revascularization for symptomatic PAD in a safety-net population was associated with low complication rates, high rates of wound healing, and relatively low major leg amputation rates in a high-risk and diverse patient population. ■

References and Acknowledgments are available with the article online:

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Online Only

Acknowledgments. Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Colorado Denver.[32-34] REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources.

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