ORIGINAL RESEARCH

PEER REVIEWED

Endovascular Treatment of Peripheral Arterial Disease and Critical Limb-Threatening Ischemia Can Be Safely Performed With 4F Arterial Access

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Abstract

Background: Peripheral arterial disease (PAD) affects over 200 million individuals worldwide, with a subset progressing to critical limb-threatening ischemia (CLTI). Endovascular revascularization is a primary treatment modality, and this study evaluates the safety and feasibility of utilizing a 4F arterial access approach for treating PAD and CLTI in an outpatient setting. **Methods:** A retrospective review was conducted on 530 endovascular procedures performed at Sunrise Vascular, a rural outpatient center, between 2019 and 2020. The study included 289 unique patients (aged 42-95 years) diagnosed with CLTI (Rutherford classification 4, 5, or 6). The primary outcome was the incidence of major complications requiring attention at follow-up. **Results:** Endovascular procedures were successfully completed with a 4F arterial access approach. The majority of cases (60.6%) utilized retrograde pedal access, while femoral access (retrograde or antegrade) was used in 38.5%. Angioplasty (96.8%) and atherectomy (95.8%) were the predominant treatment modalities. Manual compression was the primary closure method (86.4%). No major complications, unplanned amputations, or reinterventions occurred, with only 1 pseudoaneurysm and 5 minor complications reported (<1% complication rate). Radiation and contrast exposure were minimized through ultrasound-guided access and CO_2 angiography in select patients. **Conclusion:** This study demonstrates that a 4F arterial access approach enables the safe and effective treatment of CLTI in a rural outpatient setting. The low complication rate, minimal reliance on closure devices, and effective procedural techniques support the feasibility of this approach. Further studies are warranted to assess long-term clinical outcomes.

Introduction

Peripheral arterial disease (PAD) is the atherosclerotic narrowing of the arteries of the periphery of the body. This disease affects more than 200 million people worldwide.[1] In most people the disease remains asymptomatic, but in a small subset it can progress to symptoms of severe pain at rest and poorly healing ulcers, gangrene, and ultimately amputations. This subset of PAD is classified as critical limb-threatening ischemia (CLTI).[2] PAD is often classified according to the Rutherford classification[3] (**Table 1**).

Table 1. Rutherford classification of peripheral arterial disease severity

Critical limb-threatening ischemia (Yes/No)	Symptoms	Rutherford stage
No	Asymptomatic	0
No	Mild claudication	1
No	Moderate claudication	2
No	Severe claudication	3
Yes	Rest pain	4
Yes	Ulceration limited to digits	5
Yes	Severe ischemic ulceration or frank gangrene	6

The goals of CLTI treatment are revascularization to improve symptoms of rest pain, heal nonhealing ulcers, and limit amputation/tissue loss. Treatment options include endovascular revascularization, surgical revascularization, and primary amputation. There has been debate about an optimal treatment strategy,[4] but the exact treatment chosen is often dependent on several factors, including patient preference, operator skill, the patient's medical comorbidities, and the presence of a suitable vein conduit, among others.

It is estimated that between 1 and 3 million Americans experience CLTI.[5] The diagnosis of CLTI carries a 1-year mortality rate of 24% and a 4-year mortality rate of 54%, which is higher than the 4-year mortality rate of many cancers.[6] CLTI is an undertreated disease and often not treated adequately, particularly in patients from minority groups and rural areas. This may be due to the lack of access for these groups to major medical centers that are often located in larger cities and towns. In rural settings and underserved areas, outpatient centers (office-based labs or ambulatory surgery centers) of excellence have the ability to fill in the gaps of care that exist and provide treatment options where none or little currently exist.

The purpose of this study is to demonstrate that treatment of PAD and CLTI can be safely performed by keeping the arteriotomy size to 4F. This can allow such procedures to be safely performed in outpatient centers in rural settings and can help extend care when there is no major medical center available.

Materials and Methods

This study is a retrospective review of 530 procedures performed at Sunrise Vascular in the years 2019 and 2020 in a rural outpatient center. There were 289 unique patients aged 42 to 95. All patients had CLTI Rutherford classification 4, 5, or 6.

The primary outcome was whether the patient had any major complication that required attention on follow-up. Other variables studied include volume of iodinated contrast used; fluoroscopy time and radiation dose; moderate sedation medication or minimal anxiolysis used; approaches used to include antegrade or retrograde femoral access and pedal access; endovascular treatments delivered including angioplasty, atherectomy, and/or stent; and closure methods used, including manual compression or closure device.

Results

A total of 289 patients underwent 530 endovascular procedures in a rural outpatient center for treatment of CLTI symptoms in 2019 and 2020 with no major complications or unplanned amputations or reinterventions (**Tables 2, 3,** and **4**). All patients had CLTI Rutherford Class 4, 5, or 6. A mix of retrograde femoral access, antegrade femoral access, and retrograde pedal access approaches were utilized. For femoral access, closure devices were rarely utilized. Stents were rarely placed and the primary treatments performed were atherectomy and angioplasty. Anticoagulants were typically held prior to the procedure according to standard protocol (3 days for apixaban or rivaroxaban; 5 days for warfarin).

Table 2. Patient and procedural characteristics

Number of patients	289	
Number of procedures	530	
Number of procedures for Rutherford 4	392	
Number of procedures for Rutherford 5/6	132	
Age	Range, 42-95 years	Mean 70 years, SD 11 years
Weight	Range, 95-400 lb	Mean 200 lb, SD 55 lb
INR	Range, 0.90-3.80	Mean 1.13, SD 0.36
Number on antiplatelet medications (aspirin, clopidogrel)	283	% where antiplatelets held prior to procedure: 16.6%
Number on anticoagulant medications (apixaban, rivaroxaban, warfarin)	92	% where anticoagulation held prior to procedure: 91%
Systolic BP at beginning of procedure	Range, 92-234 mm Hg	
Diastolic BP at beginning of procedure	Range, 34-171 mm Hg	

Abbreviations: INR, international normalized ratio; SD, standard deviation; BP, blood pressure.

Table 3. Procedural technique

Iodinated contrast used	Mean 16 cc, SD 11 cc	

Fluoroscopy time	Mean 8.7 minutes, SD 6.2 minutes	
		Percent of total
Number of procedures in which moderate sedation was used	245	46.0
Number of procedures in which minimal anxiolysis was used	235	44.3
Access via retrograde femoral (number of procedures)	126	23.8
Access via antegrade femoral (number of procedures)	78	14.7
Access via popliteal	5	0.9
Access via retrograde pedal (number of procedures)	321	60.6
Endovascular treatment delivered – angioplasty	513	96.8
Endovascular treatment delivered – atherectomy	508	95.8
Endovascular treatment delivered – stent	20	3.8
Closure – manual compression	458	86.4
Closure – device	72	13.6

Abbreviation: SD, standard deviation.

Table 4. Outcomes

Type of complication	**Number of patients**
Acute bleeding issue/hematoma	0
Pseudoaneurysm	1
Bleeding event within 30 days (not including day of procedure)	0
Unplanned reintervention within 30 days	0
Unplanned amputation	0
Other issue (minor)	5 (soreness; ruborous toes but improved flow; pain, relook angioplasty done but no intervention; pain, no reintervention; reperfusion edema)

Discussion

For femoral access (retrograde or antegrade), we try to keep the access sheath size to 4F. We are able to deliver most treatments including atherectomy and angioplasty through a 4F sheath. This includes the Diamondback 360 Peripheral Orbital Atherectomy System (Abbott Vascular) or the Auryon Laser Atherectomy System (AngioDynamics), 0.014 and 0.018 angioplasty in 1.25-mm to 7-mm diameter sizes, and stents up to 7-mm diameter sizes.

For femoral access (retrograde or antegrade), we always use ultrasound guidance to obtain needle access into the femoral artery. We check with fluoroscopy to avoid a high stick that could risk a retroperitoneal bleed and check with ultrasound to ensure that the exact point of entry is a compressible location by tenting the anterior wall of the artery by pushing the overlying tissues down with the ultrasound probe over it. We also ensure that the site where the needle enters is free of plaque material and that the sheath is not going to be too obstructive when indwelling in the setting of bulky femoral artery plaque.

For femoral access (antegrade or retrograde), we always connect the sheath once inserted to a 'side-flush' with a steady, slow drip of heparinized saline. This reduces the chances of intra-arterial thrombus developing. We administer IV heparin up to 5000 units/kg as our procedural anticoagulation. We avoid going much higher with the heparin dosing to minimize bleeding risk and use protamine when necessary to reverse heparinization prior to access site closure. For retrograde femoral access closure, we typically use manual compression given the small bore sheath size (4F). We do not check activated clotting time at our center but try to keep the procedure time to under 90 minutes and give additional (1-2000 units) heparin after each hour of procedure time.

For antegrade access, we might access the common femoral artery or directly puncture the proximal superficial femoral artery. Again, ultrasound guidance is critically important to ensure a suitable access site. In addition to checking to ensure that the needle entry site is free of plaque and compressible, we also make it a point to access above the lesser trochanter because we believe accessing lower than this fluoroscopic landmark carries increased risk of bleeding and pseudoaneurysm. We typically do not upsize above 4F or use a closure device in antegrade access procedures.

For retrograde pedal access, we use an even smaller sheath (3/4F Rain sheath [Cordis]) where the outer diameter is equivalent to a 3F sheath but the inner diameter allows 4F compatibility with catheters, balloons, atherectomy, and stents. We believe keeping the pedal access sheath size to an absolute minimum is important to minimize access-site closure risk.

If there is a need to upsize further to deliver a therapy such as a drug-coated balloon (DCB) that is 5F compatible, we will often use a 4/5F Glidesheath Slender (Terumo) or a 4/5F Rain low-profile sheath (Cordis) to maintain the sheath size as close to 4F as possible. The 5F Halo One 45-cm low-profile sheath (BD) can allow for up-and-over delivery of 5F compatible devices while maintaining a 4F arteriotomy.

During the period of this sample of procedures, we were doing about 60% primary pedal access and 40% primary femoral access. In patients where there is high risk of bleeding due to a hostile groin (obesity, unclean groin site, bulky plaque in the femoral artery precluding safe access), primary pedal access can offer a safe and effective option.

We can additionally minimize chances of pedal access site closure by higher heparin dosage up to 9000 units/kg, keeping procedure times low (typically less than 1 hour), giving nitroglycerin at the access site, using a careful technique without too much torsional force at the access site, emphasizing patent hemostasis, and applying nitroglycerin paste to the access site after closure. When a femoral access is also present in addition to pedal access, we try to angioplasty across the pedal access site from the femoral access to ensure good angiographic flow past the access site at completion.

For all different access approaches (femoral and pedal), we always check with ultrasound before the patient is taken off the procedure table to make sure that the access site is free of any hematoma and pseudoaneurysm, and that there is good flow through the accessed artery. If there is any such issue, we take care of it before the patient leaves to recovery.

We have found that we are able to minimize iodinated contrast and radiation use by limiting digital subtraction angiography cine runs to critical treatment areas. Furthermore, we use careful radiographic technique including collimation and minimizing patient-to-detector distance to reduce radiation dose. We also minimize fluoroscopy times and lower frame rates to minimize radiation.

We use contrast diluted with heparinized normal saline (50% or less contrast) whenever possible to minimize volume of iodinated contrast used. We also employ CO_2 angiography in patients with chronic kidney disease to further reduce contrast usage. CO_2 angiography is particularly useful for visualizing arteries above the knee level, and we are able to use a reduced volume of iodinated contrast to visualize the harder-to-see infrapopliteal arteries.

Other notable items include the fact that we used atherectomy and angioplasty as our primary treatment modality (approximately 95% of procedures), and we had a very low stent utilization rate (about 4%). Orbital atherectomy and laser devices are available in 4F sizes and, using these, we are able to treat both femoropopliteal and tibial arterial segments.

In this series, we were not using DCBs because of our goal to keep the access to 4F sheath size as much as possible (there are no DCBs available that are compatible with this sheath size). We do currently upsize to 5F to deliver DCBs in our practice as needed, and will typically close with the 5F Celt closure device (Vasorum) and are able to maintain a 4F arteriotomy utilizing low-profile sheaths.

Since we typically use small bore 4F access, our primary closure method was manual compression (86%), and a closure device was only used in a minority of cases (14%). Keeping the arteriotomy to 4F greatly improves hemostasis with manual closure and minimizes chances of complications such as hematomas and pseudoaneurysms. We had 1 pseudoaneurysm and 5 minor complications, which is a less than 1% complication rate. We had no major complications and did not require any hospital transfers.

We were also able to minimize iodinated contrast and radiation usage by utilizing extravascular ultrasound extensively and minimizing our digital subtraction angiography runs to areas of interest. A limitation of this study is that it did not examine long-term clinical outcomes, which is outside its scope. However, the percent of technical success was high, and only a small minority of patients (<5%) required reintervention within 1 year.

Conclusion

CLTI carries high morbidity and mortality rates. The disease is undertreated, particularly in underprivileged minorities and lower socioeconomic groups. As demonstrated in this study, use of 4F arterial access and careful technique can allow for the safe and effective delivery of endovascular treatment of CLTI to patient populations in rural settings where there is limited access to major medical centers.

Adequate treatment of CLTI involves a multidisciplinary approach with primary care, wound care, podiatry, endocrinology, pain management, etc. Open surgery plays an important role in the care of these patients but can be limited by lack of access in rural settings, patient comorbidities and preference, and lack of adequate vein for bypass. Ongoing clinical follow-up to ensure good clinical outcomes for patients is important as there is no cure for this deadly disease. ■

Affiliations and Disclosures

Sreejit Nair, MD, and Ashwanti Sastry, MD, are from Sunrise Vascular Center in Cary, North Carolina; Joseph Puma, DO, and Justin Ratcliffe, MD, MBA, are from Sorin Medical in New York, New York.

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