Sizing for Success With Shockwave IVL

Shockwave IVL Mechanism of Action

Dr. Varshana Gurusamy
Assistant Professor, Interventional Radiology, MD Anderson Cancer Center
Dr. Patrick Harty
Interventional Radiologist, Radiology Consultants of the Midwest, Omaha, NE

The endovascular treatment of calcified peripheral arterial disease is complex and though there are various tools used in its treatment, many carry risks of complications. Intravascular lithotripsy (IVL) has proven to be a safe and effective therapy for treating calcified atherosclerosis.[1,2] It is derived from extracorporeal lithotripsy treatment of nephrolithiasis and similarly utilizes sonic pressure waves to fracture calcium within blood vessels. In the vascular setting, these pressure waves are released from emitters on a balloon catheter. The sonic pressure waves create microfractures in intimal and medial calcium, resulting in improved compliance and luminal gain without added risks of distal embolization or vessel perforation.[3]

While it is easy to draw comparisons between percutaneous transluminal angioplasty (PTA) and IVL, they differ greatly in their mechanisms of action. Angioplasty involves creating micro-dissections in an effort to increase luminal diameter. However, there is a risk of dissection, bailout stenting, and distal embolization with angioplasty.[2,4] Vessel injury can also be seen with atherectomy.[5] Conversely, IVL's mechanism of action does not involve actively dilating a vessel. Rather, the cornerstone of intravascular lithotripsy is establishing wall apposition of the balloon delivery system and the vessel/lesion to be treated. The indeflator of the IVL catheter is prepped with dilute contrast, similar to PTA. The catheter is then inflated to a sub-nominal pressure (2-4 atm), a key differentiator from PTA, with the goal of achieving wall apposition.

The sonic pressure waves travel from the emitters in the balloon creating a vapor or cavitation bubble, which releases secondary shockwaves. Because the shockwaves have a similar acoustic impedance as vascular endothelium but a different impedance than calcium they safely pass through the vessel wall and fracture the calcium in situ. Fracturing calcium in the vessel wall leads to a more compliant vessel and increased luminal gain.[6]

Sizing of the IVL catheter is critical to achieving the ideal treatment. In traditional angioplasty, the balloon is sized 1:1 to the reference vessel diameter. In contradistinction, IVL catheters are sized 10% larger than the reference vessel diameter (RVD) which allows for optimal delivery of the shockwaves.

Is it safe to oversize by 10% with Shockwave IVL?

As endovascular specialists, we can often be wary of oversizing devices in the periphery, particularly since complications in lower extremity cases can be quite spectacular and very unforgiving. Perforations, flow-limiting dissections, emboli, and occlusions all can occur in a split-second, and we all can likely recall cases that doubled in time and effort due to sizing errors. Most of us have learned the hard way not to cavalierly oversize or overinflate angioplasty balloons, lest we risk rupture or significant dissection.

Fortunately, with IVL, concern for these misadventures is negligible, because significant complications with IVL have all been shown to be less than 1% (Figure 1)[1,2].

	DISRUPT PAD III RCT[1]	DISRUPT PAD III OS[2]
N	153	1367
Vessels	SFA/Pop	Iliac, CFA, SFA/Pop, Infrapop
Dissection (Type D-F)	0%	0.7%
Perforation	0%	0.2%
Embolization	0%	0%
Slow Flow/No Reflow	0%	0%
Abrupt Closure	0%	0%
Thrombus	0%	0%
Final Angiographic Complications (Core-Lab)		

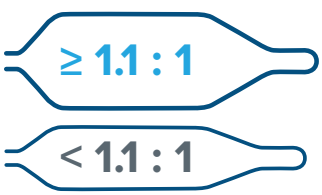
Figure 1

The Shockwave device has been specifically designed to safely be used with a 10% oversize and with a 1 cm therapeutic overlap. Oversizing helps achieve optimal wall apposition for sonic pressure wave delivery but does not risk rupture or other complications due to the low pressures at which IVL is employed. Primary patency rates are improved by 15% when proper technique is carefully followed, including oversizing (Figure 2)[1].

IMPROVED STENOSIS REDUCTION

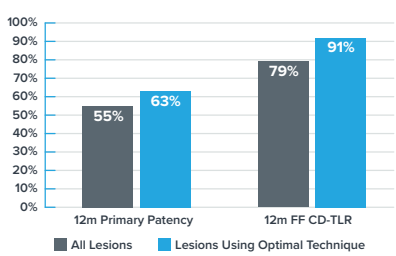
— Per a multivariable analysis in the PAD III Observational Study (n=1373), oversizing by 10% or greater was an independent predictor of improved stenosis reduction but not a predictor of complications[1]

IVL BALLOON-TO-ARTERY RATIO



IMPROVED PATENCY

— Optimal IVL technique (including oversizing by 10%) was associated with 15% improved primary patency & rate of CD-TLR in PAD II[2]



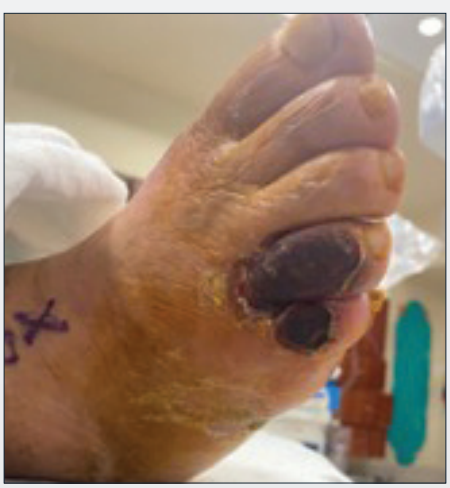
*Optimal IVL technique included oversizing IVL device by 10% vs. the RVD and overlapping treatment segments by 1cm to avoid therapeutic miss.

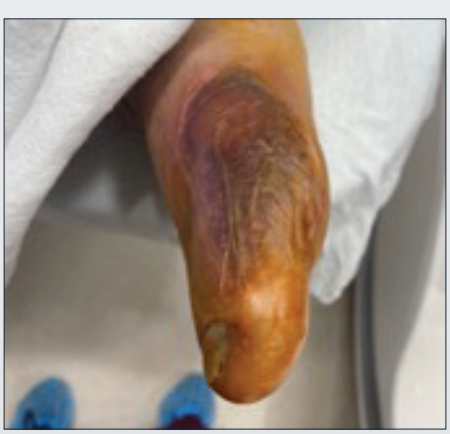
Figures 2

With this knowledge, it becomes crucial to take a few extra moments to accurately measure vessel diameters prior to intervention to achieve the best results. Our process is to measure vessel diameters from the DSA images using the on-screen tools, intravascular ultrasound at the time of intervention, or from CTA images obtained prior to the day of the procedure.

Popliteal Disease in CLTI Patient

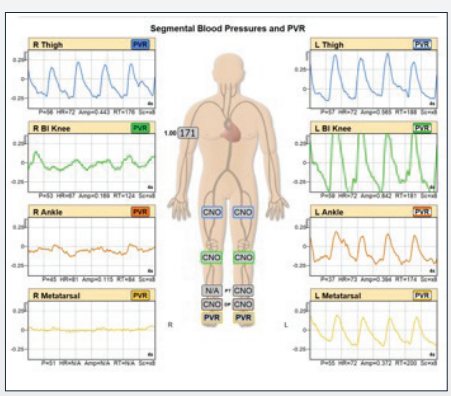
A 59-year-old man with a history of insulin-dependent diabetes and end-stage renal disease on hemodialysis presented with a non-healing ulcer on his right foot. He has a prior history of 4th and 5th-digit amputations of his left foot and prior deep venous thrombosis for which he takes 2.5 mg apixaban twice daily. He is not currently taking any antiplatelet therapy but does take 40 mg of atorvastatin daily. (Figures 3-4)

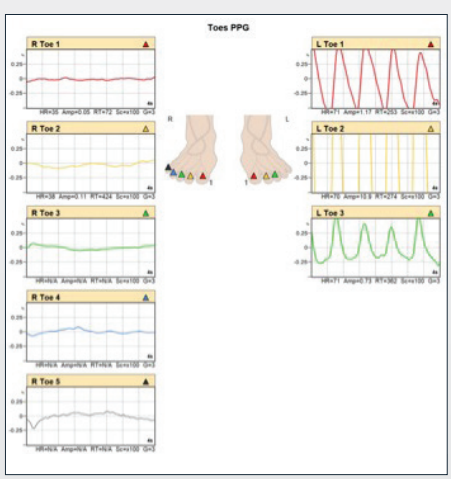




Figures 3-4

Noninvasive imaging of his lower extremities demonstrates dampening of the right below-the-knee waveforms consistent with femoropopliteal disease. This is confirmed on arterial duplex, where there are tardus parvus (TP) waveforms in the right proximal popliteal artery. Cross-sectional imaging can be helpful in pre-procedural planning. Though we did not expect any inflow disease based on his pulse volume recordings or arterial duplex in this particular case, this does help plan access and patient positioning. (Figures 5-6)





Figures 5-6

SHOCKWAVE PERIPHERAL IVL

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Images from our patient's angiogram echo his physiologic imaging, a heavily calcified popliteal artery. There is diminished flow to the foot without a demonstrable tibial vessel target for revascularization suggesting that improving the inflow from his popliteal artery would likely be the best treatment strategy.

Procedure:
Antegrade right common femoral artery access was obtained, and the lesion was crossed successfully. The diameter of the uninvolved popliteal artery measured 4 mm and a 5.0mm x 60mm Shockwave catheter was chosen. The balloon was initially moved distally to proximally and the vessel was treated in overlapping segments using all 10, 30-second pulse cycles. (Figure 7). A post-IVL angiogram demonstrates a marked improvement in luminal gain. (Figure 8)

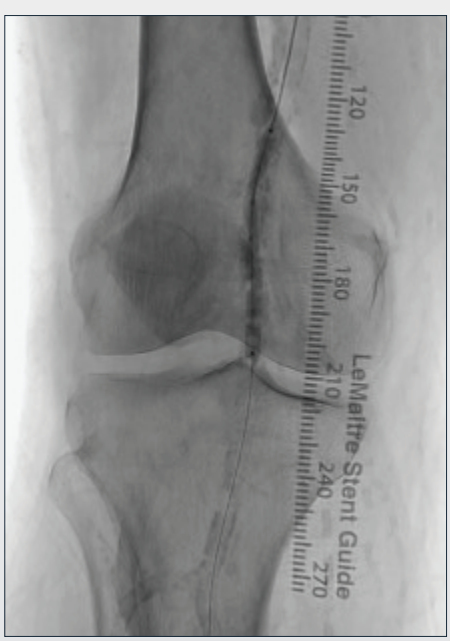


Figure 7

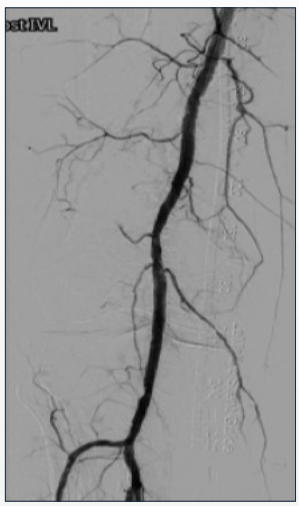


Figure 8

In an effort to optimize treatment in this patient with critical limb threatening ischemia, the lesion was further treated with a 5 mm drug-coated balloon. Post-treatment angiograms demonstrate improved flow in the below-the-knee runoff.

Perfusion software can also be helpful in visually demonstrating improved blood flow. (Figure 9). Additionally, post-intervention duplex demonstrated improved flow.

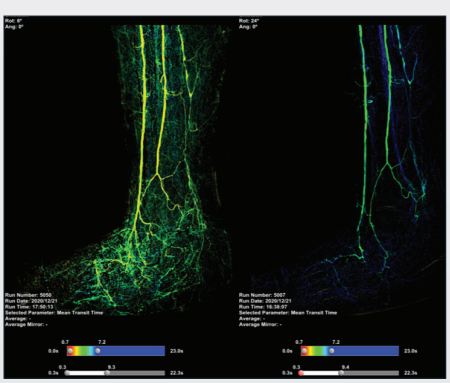


Figure 9

Discussion
Sizing the treatment balloon to 10% larger than RVD can seem unintuitive initially. Indeed, for most vascular specialists the inclination from PTA is to size 1:1. Understanding that the IVL balloon is inflated to sub-nominal pressure allowed me to become more comfortable with intentional oversizing. I often use angiography or intravascular ultrasound to size the reference vessel on the table. I usually have an idea of the RVD from pre-procedural imaging and will ask to have several IVL size options in the room. I typically use all the pulses and cycles and have not yet needed to use more than one IVL catheter in treating a single lesion. The treatment of CLTI is complex and mitigating the treatment of calcified lesions with the risk of vessel injury is challenging. I have gravitated towards IVL due to the high safety profile (DISRUPT data) and its effectiveness in luminal gain as a standalone or prior to DCB or stenting[2].

Below-the-Knee Disease in CLTI Patient

Case Review:
The patient is a 76-year-old female with longstanding diabetes mellitus, second-hand smoke exposure, underlying myelodysplastic syndrome, peripheral arterial disease with chronic limb-threatening ischemia (CLTI), recent left third toe amputation secondary to gangrene, and delayed wound healing over 6 months.

On physical exam, her left common femoral artery is palpable, but her popliteal, dorsalis pedis (DP) and posterior tibial artery pulses are not. Her dorsalis pedis artery is audible by Doppler, but her posterior tibial artery is not. Her most recent arterial duplex ultrasound demonstrates elevated velocities in the left popliteal artery consistent with significant stenoses, occluded posterior tibial and peroneal arteries, and a mid-anterior tibial artery occlusion. Waveforms are monophasic from the popliteal artery distally, with diminished velocities as well.

Procedure:
She was brought to the angiography suite, and access was gained into the left common femoral artery using antegrade ultrasound-guided micropuncture technique. Her initial diagnostic angiogram demonstrates a patent common femoral and superficial femoral artery. There are multifocal calcified moderate and severe, long and short-segment stenoses within the popliteal artery (Figure 10).

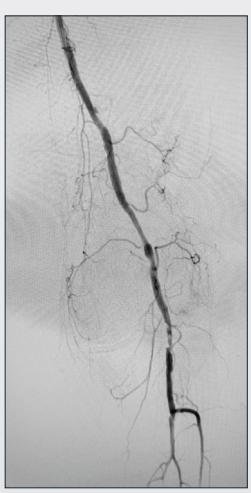
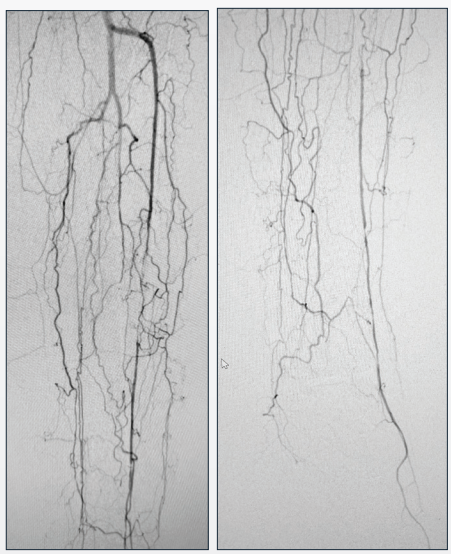


Figure 10

The lower leg angiogram demonstrates occluded posterior tibial and peroneal arteries, an occluded and calcified mid anterior tibial artery, and a runoff to the foot primarily via the anterior tibial artery (Figure 11a and 11b).



Figures 11a & 11b

A 6 French x 25 cm sheath was placed at the access site, and 5000 units of IV heparin was administered. The popliteal artery lesions were crossed using a 4 French MPA catheter and a 0.035 inch Bentson guidewire. The occluded mid-anterior tibial artery was then crossed using an 0.014 inch Hi-Torque Command guidewire and an 0.014 inch Quick Cross Catheter.

Vessel diameter measurements were then made using the onscreen workstation tools, and the Shockwave balloon diameter was selected with a > 10% oversize to optimize wall apposition for IVL. Intravascular lithotripsy of the multifocal left popliteal artery stenoses was then performed using a 5.5 mm x 60 mm Shockwave M^{5+} balloon.

A total of 300 pulses were delivered with overlapping inflations (Figure 12).

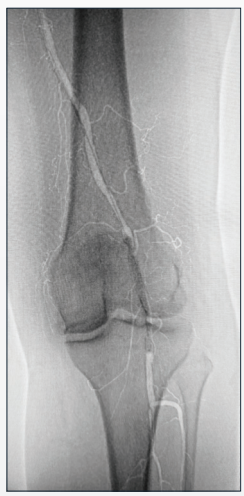


Figure 12

Drug coated balloon angioplasty of the treated popliteal artery was then performed using a 5 mm x 200 mm Ranger balloon at low atmospheres with prolonged inflation. Post IVL/DCB angiography demonstrates significant improvement in blood flow and vessel diameter, with no significant residual stenosis, and most importantly, no flow-limiting dissection (Figure 13).

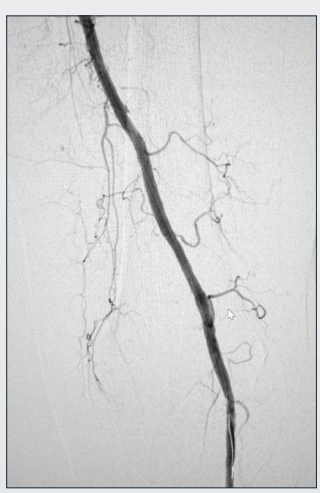


Figure 13

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Attention was then turned to the mid-anterior tibial artery occlusion. Vessel diameter measurements were then made using the onscreen workstation tools, and the Shockwave balloon diameter was selected with a > 10% oversize to optimize IVL treatment. Intravascular lithotripsy of the occluded segment was then performed using a 2.5 mm x 40 mm Shockwave S[4] balloon for a total of 160 pulses using overlapping inflations (Figure 14).

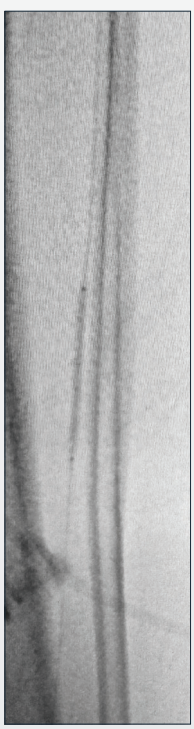

Figure 14

200 mcg of intra-arterial nitroglycerine was delivered, followed by 4 mg of intra-arterial TPA to treat the distal left foot microvasculature. Prolonged inflation low-pressure angioplasty of the anterior tibial artery was then performed using a 2 mm x 220 mm Coyote angioplasty balloon to treat any underlying spasm.

Final angiography demonstrates restoration of in-line outflow to the foot with no significant residual stenosis or significant dissection (Figure 15a and 15b).

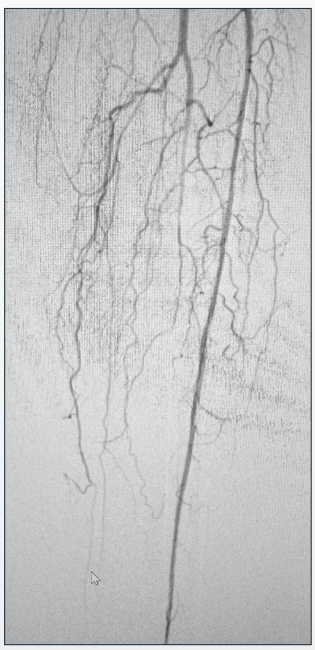

Figure 15a

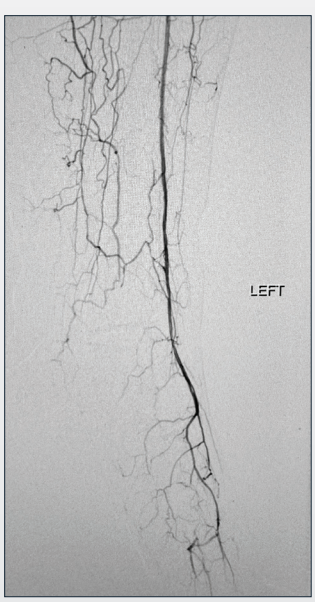

Figure 15b

The patient was noted to have a strong DP pulse in the recovery area immediately following the procedure.

Follow up:
The patient was continued on her current medical therapy of Aspirin 81 mg daily and Xarelto 2.5 mg BID (per the VOYAGER PAD protocol)[7]. She noted significant improvement in her left lower extremity symptoms at her 2-week follow-up visit. Her toe amputation site healed entirely within the next 4 weeks.

Discussion:
This case demonstrates the safety and effectiveness of the Shockwave catheter in achieving limb preservation while minimizing complications such as dissection and distal embolization. This safety profile is particularly important in patients with single vessel runoffs and nonhealing wounds, as the overall risk of amputation in patients with CLTI is very high.[8] It also minimizes bailout stenting (75% reduction) in vascular beds that have suboptimal stent outcomes such as the popliteal and tibial arteries. The risk of significant (type C or worse) dissection is reduced by 77% when using IVL vs POBA, and required pressures are also 44% lower to achieve even better luminal gain (15.4% better than POBA).[2] Other devices such as atherectomy could be considered in this case, but with an added risk of distal embolization and with limited ability to use a distal protection basket. For all these reasons, this patient was an ideal candidate for endovascular intervention using the Shockwave system.

Conclusion:

Shockwave IVL has become an essential tool for our PAD / CLTI interventions, particularly where limb salvage is of critical importance in our practices. Over time and with more experience with IVL, we have found that balloon diameter selection is a crucial step in the process for IVL, as a greater than 10% diameter oversize is associated with a 15% improvement in primary patency and freedom from clinically driven target-lesion revascularization.[9] We measure from our DSA images using onscreen tools at the time of intervention, real-time intravascular ultrasound or using prior CTA images. The safety and effectiveness of Shockwave IVL makes it an ideal device for high-risk limb salvage PAD interventions.

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Dr. Harty and Dr. Gurusamy are paid consultants of Shockwave Medical.

In the United States: Rx only.

Indications for Use—The Shockwave Medical Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

Contraindications—Do not use if unable to pass 0.014" (M5, M5+, S4) or 0.018" (L6) guidewire across the lesion-Not intended for treatment of in-stent restenosis or in coronary, carotid, or cerebrovascular arteries.

Warnings—Only to be used by physicians who are familiar with interventional vascular procedures—Physicians must be trained prior to use of the device—

Use the generator in accordance with recommended settings as stated in the Operator's Manual.

Precautions—use only the recommended balloon inflation medium—Appropriate anticoagulant therapy should be administered by the physician—

Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology.

Adverse effects–Possible adverse effects consistent with standard angioplasty include–Access site complications –Allergy to contrast or blood thinner–

Arterial bypass surgery—Bleeding complications—Death—Fracture of guidewire or device—Hypertension/Hypotension—Infection/sepsis—Placement of a stent—renal failure—Shock/pulmonary edema—target vessel stenosis or occlusion—Vascular complications. Risks unique to the device and its use—Allergy to catheter material(s)— Device malfunction or failure—Excess heat at target site.

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events. **www.shockwavemedical.com/IFU**

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