Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist

CATH LAB SPOTLIGHT

Wayne Memorial Hospital

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Tell us about your cath lab and facility. What drove the need to implement a cardiac cath/percutaneous coronary intervention (PCI) program?

Wayne Memorial Hospital (WMH) is a small, independently owned, rural community hospital with just under 100 beds. We are a standalone cath lab Level 2, meaning we do not have an on-site open heart program. We are located in the Poconos mountain range where cell service is spotty. Many patients drive to the emergency department, as they feel it is quicker than calling an ambulance (this is definitely not something we promote — ever!). In addition, the population around Honesdale, Pennsylvania, doubles in the summer. Summer homes around the lakes are filled, along with many summer camps, bringing both children and adult staff members from city areas to the mountains for retreat. Hence, our cardiac business increases.

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CALCIUM CORNER

Taking a Pulse Check in Complex Calcified Vessels

CLD talks with Jaikirshan J. Khatri, MD, FACC, FSCAI.

Dr. Khatri is the Director of Complex Coronary Intervention at Cleveland Clinic, performing 150-200 chronic total occlusion (CTO) procedures annually, along with a high volume of complex and high-risk coronary intervention procedures (CHIP).

Can you describe your approach to evaluating arterial calcium?

Conservatively, at least 90% of our cases utilize intravascular imaging. We try to image lesions up front to have a better idea of what we are facing. There are broad categories we can use to describe the type of calcium we are dealing with, such as focal, diffuse, thin cap, thick, nodular, limited arcs of calcium, and concentric calcium. These categorizations help us decide what modality will be most useful. Device use is predicated on the anatomy, as well as our options of what we can deliver to assess the lesion.

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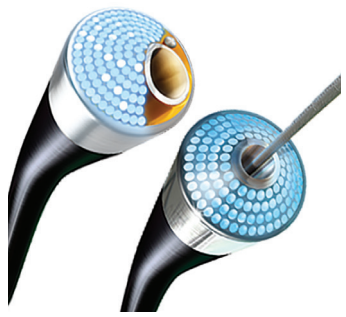
OFFICE-BASED LABS

Out-of-Hospital Lower Extremity Intervention in Severe PAD: How the Right Equipment and Devices Support Limb Salvage

CLD talks with Douglas Redd, MD, and Liese Redd, Practice Manager.



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Taking a Pulse Check in Complex Calcified Vessels

CLD talks with Jaikirshan J. Khatri, MD, FACC, FSCAI.

For diffuse disease that spans a very large segment of an artery, where we can't even deliver balloons, we will probably treat with an atherectomy device up front, then use intravascular imaging and decide what else needs to be done. For an area that is angiographically calcified, somewhat focal but not very tight and stenosed, then we will use intravascular imaging up front to determine the calcium arc and thickness. That information helps us to determine whether we can treat with a noncompliant balloon, cutting balloon, or intravascular lithotripsy (IVL).

How do you know when you have successfully modified calcium with intravascular lithotripsy?

If we have imaging data, then after IVL, we will go in with a one-to-one noncompliant balloon and see how the lesion responds to a balloon inflation of up to 20 atmospheres (atm). We will do what is called a rotational angiogram, where we put the fluoro on and swing the C-arm around at least 60 degrees to see if there is any waist in the balloon. If we don't see much of an appreciable waist, we are comfortable with stenting that artery.

Before we were totally comfortable with this concept, we would always image after IVL use, looking for cracks in the arcs of calcium. If you can get the IVL catheter into a lesion, then you should then be able to get an imaging catheter into the lesion. With optical coherence tomography (OCT), the challenge is that it doesn't see very deeply in the artery (often the calcium micro-fractures are too deep in the arterial wall to be seen with OCT), so you can't always tell where there are cracks. I think it is easier to use intravascular ultrasound (IVUS). Although IVUS can't see through calcium, cracks will appear as little rays of light extending into the deep layers of the artery, making it into areas that used to be dark shadow (see Figure). These are a good indication. In the beginning, visualizing these cracks can be subtle and a little intimidating, and this is where a one-to-one noncompliant balloon and doing the C-arm swing is helpful, especially when you are not confident about what you are seeing on imaging. If a noncompliant balloon that used to have a waist in it, now inflates with no waist, then you can feel comfortable that your stent is going to expand as well. If we see any sort of a waist in the noncompliant balloon, or if we image and don't see that the calcium has been cracked, then our workflow involves, typically, going back in with either a cutting balloon or IVL, or rarely, atherectomy, if it is a focal area.

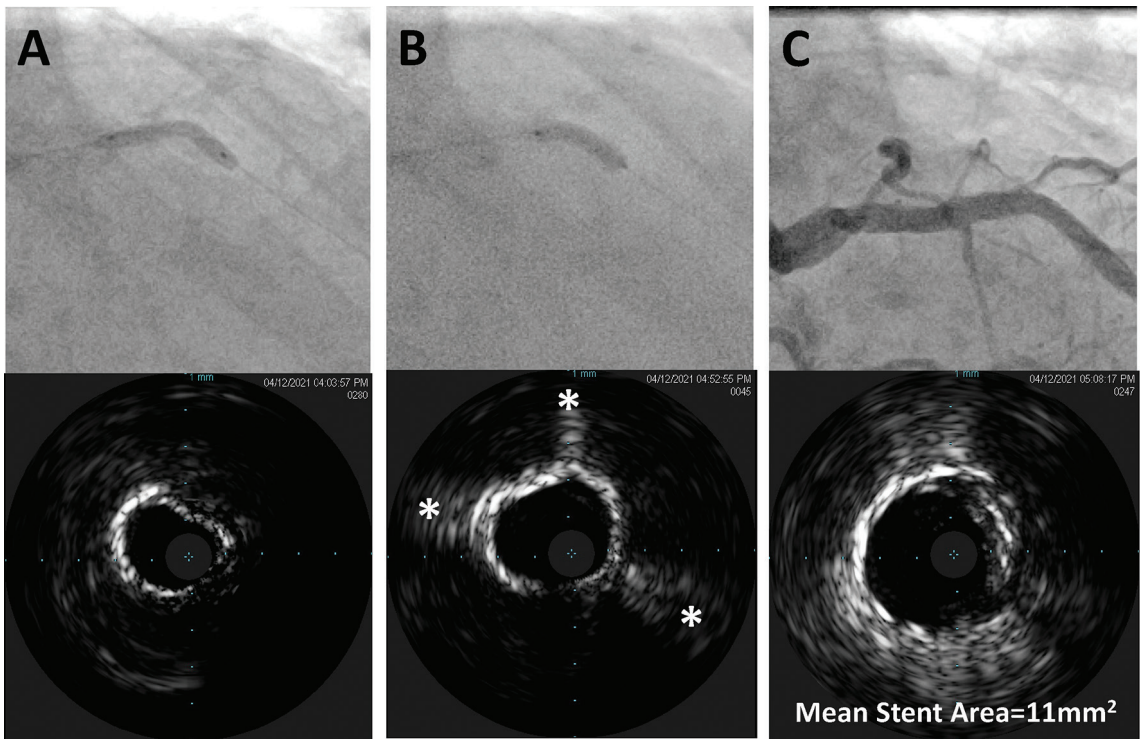

Figure. (A) Heavily calcified coronary lesion as shown by intravascular ultrasound (IVUS) would not yield to pre-dilatation using a 3.5 x 15 mm noncompliant balloon. (B) Lesion was further treated with a 3.5 x 12 mm Shockwave balloon with fluoroscopic resolution of stenosis after 40 pulses were delivered. IVUS confirmed cracked calcified plaque as indicated by asterisks. (C) Excellent stent expansion as confirmed by IVUS.

Considering best practices, do you feel it necessary to use all pulses available? If not, how often do you find yourself using all 80 pulses?

Much of this decision, at least in the United States, is based on reimbursement codes. In an elective percutaneous coronary intervention (PCI), Medicare outpatient coverage is for three IVL devices, giving us 240 pulses for most patients. Obviously, we will do whatever is necessary to complete the case. From a financial standpoint, in terms of what works for the healthcare system and the budget of the cath lab, you can get away with two IVL devices. If there is a focal lesion, we don't worry about rationing pulses. We give all 80 pulses at the focal area and then return with imaging, or with a one-to-one noncompliant balloon to see if there is any more waist in the balloon, and then we can move on. If there is more diffuse disease, we like to use intravascular imaging to identify where the arc and thickness is the most concerning, and we will isolate our pulses to those areas. Based on the imaging, we will split the 80 pulses throughout the areas we are most concerned about. We return with a one-to-one balloon or will use intravascular imaging to see if there are any other areas that are still refractory to dilation. It is a stepwise approach: I will use one IVL device and a one-to-one noncompliant balloon. If the image is not satisfactory, then I will go back in with the second IVL catheter. I spread pulses across wherever the imaging indicates that we need help. I don't think you always see the IVL balloon fully expand as it is delivering the pulses, but it is still acting on the calcium. We have seen this to be true on many occasions, where there is clearly a waist in the IVL balloon and we have only delivered 20-30 pulses, yet when we go in with the one-to-one noncompliant balloon, the artery expands just fine. I think it is acceptable to conserve pulses, particularly if you have diffuse disease. If there is very focal disease, that decision is irrelevant, and you can use all the pulses. I don't think I would ever use less than the maximum pulses. You bought the device; go ahead and use all the pulses. I don't think there is any real downside to that, other than the time it takes to give the pulses. IVL does 10 pulses over 10 seconds of inflation and then has a mandatory pause before you can give 10 more pulses. If you are impatient, you might say, "I've administered 40 pulses and we are good," but I don't consider that a good way to use this resource. I like to use all the pulses once I have opened the device.

You mentioned sometimes seeing a waist in the IVL balloon. How does that affect your consideration of IVL's impact?

Seeing a waist is not an indication that the IVL didn't work. The balloon only goes up to four atmospheres as it is delivering the pulses, but the theoretical atmospheres of administered energy are well beyond what a conventional balloon can do. While you may not see the waist disappear, microfractures are happening as that energy is delivered, and when you go in with a conventional noncompliant balloon, you will be pleasantly surprised at how well it expands.

I don't use the IVL balloon's angiographic behavior as an indication of whether IVL worked. I use either intravascular imaging or a one-to-one noncompliant balloon to verify that we modified the calcium.

Can you talk more about how calcium is affected by the fractures caused by IVL?

Using IVL brings a fundamental change in the compliance of the lesion. The trials run by Shockwave have indicated that there are actually microfractures that are visible on computed tomography but are outside the visible resolution of either OCT or IVUS. When you go back in with a noncompliant balloon, the lesion is much softer, yet you may not see cracks on intravascular imaging. The cracks that you do see on intravascular imaging are very large fractures, relatively speaking. It means you now have an area where the balloon will be able to push into. You may have a shelf of calcium that is 180 degrees and might not really expand much at all. But if you see some cracks on the edges, you know that the balloon is going to expand in those areas. You might get an eccentric expansion, a D-shaped lumen, let's say. You will still get the minimum stent area for a good clinical result. I would emphasize that you are not going for a perfectly round stent expansion in these cases. What you are going for is adequate stent area and that may result in an eccentric expansion. A good example would be a calcific nodule. A calcific nodule is just the tip of the iceberg of a much, much larger hunk of calcium that is deep in the artery wall and is never going to move. All you can do is modify the tip of that iceberg, either with atherectomy by shaving some of it off, or with IVL, by softening some of it up by fracturing it. When you inflate a noncompliant balloon, it will expand in the shape of a D. There is no way you are going to move that deep calcium. It is going to stay, but the rest of the artery will be much more compliant and will accommodate the device that you are trying to expand. None of the data that we have thus far, from the long-term follow-up of intravascular imaging trials, indicate that a good outcome has anything to do with a round expansion. It has to do with minimum stent area, whether it is shaped like a D or whether it is perfectly circular.

Any final thoughts?

In 2008, when I first started attempting to treat these very complex lesions, we were using neurointerventional devices to try to finagle our way through CTOs. We would run down to the interventional radiology suite to see what we could pilfer from their shelves. Now we have a whole array of dedicated devices and a whole cohort of people with specific training in the field who are coming up with great new ideas of their own, and new devices that are in development. The sky's the limit and I can't even imagine where we are going next. The combination of technology and dedicated training is allowing us to keep up with this new challenge, and it is exciting. Our understanding of how important it is to modify calcium and use intravascular imaging will help catapult some of this development forward.

The biggest message that I would share is that IVL is a complementary solution within a larger portfolio of devices to manage calcium. You need to know how to use all of these devices, as well as how to interpret intravascular imaging, to properly take care of these patients. Our patients are older, they are sicker, and they have often had bypass surgery. Their disease is much, much more complex than it was 15 years ago. IVL is a game changer, in terms of dealing with patients who have very specific problems. It is not the only way that you are going to deal with calcific disease, but IVL can simplify problems that otherwise are relatively risky to deal with. ■

This article is sponsored by Shockwave Medical. Dr. Khatri is a paid consultant for Shockwave Medical. See Important Safety Information below.

Learn more about coronary intravascular lithotripsy use by visiting Cath Lab Digest's Calcium Corner. Click on the QR Code or start at cathlabdigest.com:
CLD home page –> Topics –> Calcium Corner

Use this QR code to access the Calcium Corner directly.

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Important Safety Information

In the United States: Rx only.
Indications for Use — The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C² Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

Contraindications— The Shockwave C² Coronary IVL System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries.

Warnings— Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy.

Precautions— Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anticoagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target lesion.

Potential adverse effects consistent with standard based cardiac interventions include– Abrupt vessel closure - Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy-Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion-Cardiopulmonary arrest-Cerebrovascular accident (CVA)-Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or non-emergency coronary artery bypass surgery-Emergency or non-emergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention-Hematoma at the vascular access site(s)-Hemorrhage-Hypertension/Hypotension-Infection/sepsis/fever-Myocardial Infarction-Myocardial Ischemia or unstable angina-Pain-Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke-Thrombus-Vessel closure, abrupt-Vessel injury requiring surgical repair-Vessel dissection, perforation, rupture, or spasm.

Risks identified as related to the device and its use: Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture.

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

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C² Coronary IVL system instructions for use containing important safety information.