Cath Lab Digest

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

CLINICAL UPDATE

STAT2 Results: 1-Hour Radial Hemostasis Protocol Safely Shortens Time to Ambulation, Aiding in Same-Day Discharge

CLD talks with Arnold H. Seto, MD, MPA, and Jordan G. Safirstein, MD, Co-Investigators, STAT2 Trial.

Can you describe the STAT2 study?

Arnold H. Seto, MD, MPA: This trial was an unsponsored, investigator-initiated study to follow up on an earlier pilot study testing StatSeal® (Biolife, LLC), a potassium ferrate hemostatic patch (Figure 1), as an adjunct to compression with the TR Band® (Terumo) for transradial catheterization.[1,2]

The STAT2 trial is a follow-up study that enrolled 443 patients and attempted a full deflation of the TR Band at 60 minutes for both arms of the study, which offered more of an apples-to-apples comparison than the pilot study.

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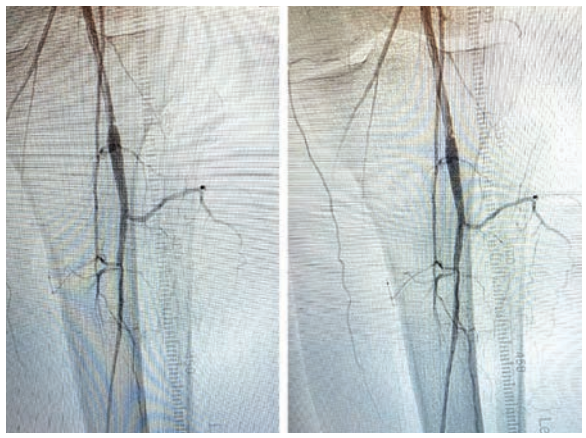
PERIPHERAL ARTERIAL DISEASE

Building an Algorithm for Success: Treating CTLI in Central Georgia

CLD talks with Jason R. Chapman, MD.



Can you tell us about your work and institution?

I am a board-certified vascular surgeon who is employed with Atrium Health Navicent Medical Center, a 637-bed level I trauma center located in Macon, Georgia. The hospital serves as the primary academic facility for Mercer University School of Medicine. The Medical Center serves a population of over 750,000 patients from a surrounding 30 counties. It is the second-largest hospital in the state, with approximately 140,000 patients per year encountering our emergency department. In my practice, I manage and treat patients with peripheral artery disease, carotid artery disease, aortic disease, venous disorders, and hemodialysis access, as well as perform multilevel spine exposures.

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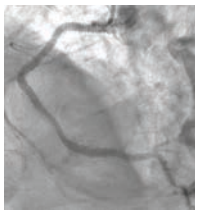
CALCIUM CORNER

Coronary IVL Tips and Tricks



CLD talks with Andrew J.P. Klein, MD, FACC, FSVM, FSCAI.

Could you describe your lab and practice?

I am at Piedmont Heart and Vascular Institute in Atlanta, a major coronary and peripheral intervention center and high-volume lab that is also the central location for Piedmont Healthcare's heart valve program. We receive a high number of referrals from around Georgia. Piedmont Heart Institute has 8 labs: 2 dedicated peripheral labs and 6 coronary labs with 2 dedicated to structural heart interventions.

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Coronary IVL Tips and Tricks

CLD talks with Andrew J.P. Klein, MD, FACC, FSVM, FSCAI.

We also have 2 dedicated hybrid ORs for the treatment of structural heart disease and another 6 cardiothoracic rooms. Georgia has traditionally had issues with access to care, which means we see a lot of advanced vascular disease and regularly treat heavily calcified vessels, both coronary and peripheral.

How often do you know in advance of a procedure that you will be encountering a high level of calcium?

It depends if it is a referral to do a complex percutaneous coronary intervention (PCI) or a de novo lesion. When we have baseline images from either our own system or an outside system, we can plan ahead and know what we are walking into, and have a strategy in terms of staged atherectomy or intravascular lithotripsy (IVL) (Shockwave Medical). We try to avoid de novo atherectomy, which would be a situation where you come across a heavily calcified vessel during a diagnostic procedure and decide to treat it, because I do think there is an issue of medical-legal risk. Atherectomy is definitely complex and even though we use it routinely, we have discussions with patients before we start work with advanced devices. IVL is a different story, however, because if you can blow up a balloon, you can use this device. I believe that with the safety profile of IVL, we have an option in this situation that otherwise may require a staged procedure. What I mean is that in cases where the lesion does not release with the balloon, previously we may have considered stopping and bringing the patient back for a staged atherectomy procedure. With IVL, if you can get the balloon across the lesion, you can now effectively treat the calcification. Complications can happen in heavily calcified vessels and therefore, it is my practice to stage these procedures or have a priori discussions about atherectomy and/or IVL in advance, simply to be more transparent about the risk associated with this challenging lesion subset.

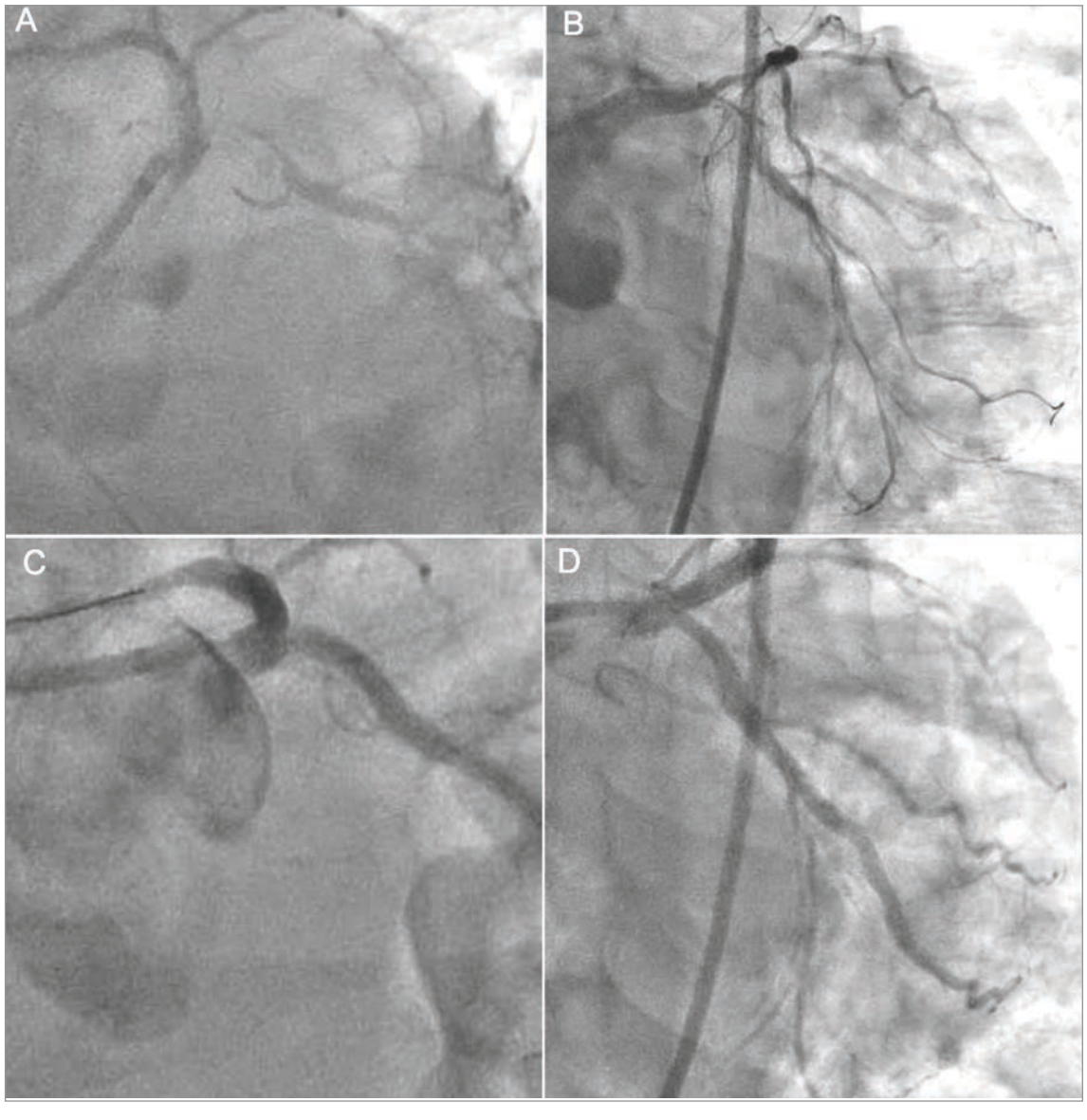

Figure 1. Efficacy of intravascular lithoplasty (IVL). (A-B) Baseline angiography showing severe ostial and proximal circumflex and proximal left anterior descending (LAD) coronary artery disease in an elderly male with class III angina turned down for bypass. IVL was used to treat the ostium of the circumflex and LAD (one balloon in this case, a 4 mm x 12 mm) after predilatation using a non-compliant balloon and then stenting using the DK crush technique with proximal optimization. (C-D) Final angiography in oblique views showing excellent stent expansion. Intravascular ultrasound was used to guide the intervention and care was made not to oversize the ostial/proximal circumflex, given the poststenotic dilatation present at baseline.

Can you share some of your approaches to different types of calcific lesions in the coronaries?

Concentric lesions respond really well to IVL, meaning specifically when one visualizes a 360-degree arc of calcium on intravascular ultrasound. Even baseline films may not allow us to tell what is adventitial and what is intimal, so we will use intravascular ultrasound to define that calcium and then pull out IVL for the intervention to optimize our stent outcomes. IVL works well in eccentric lesions and I find it particularly useful in angulated segments. This is especially true in the proximal circumflex bend, where there is a high risk of perforation using atherectomy. IVL is ideal here. Nodular calcium, so-called 'popcorn calcium', is a little more challenging. We don't really have anything that treats nodular calcium extremely well, but probably atherectomy may have an edge, just because it can be used more focally on that lesion. Again, it all depends upon the lesion and its angulation, and the type of calcium present. When we have bad calcium, where the wire may drive the atherectomy device into the wall of the vessel, I will move to IVL. In extreme calcium where the IVL catheter is not even able to be delivered to the target lesion, we sometimes use rotational or orbital atherectomy first and then move to IVL. No one shoe fits everyone. You just have to figure out what fits for your patient at that time.

Do you have any tips to share with people who are just starting to use IVL?

First, the most important thing about the device is a very good preparation of the balloon. You have to have a negative prep that is similar to that of a valvuloplasty balloon, which I think is the best way to describe it. IVL requires the medium to send the sound energy. If there is air in that line, you are not going to get the same efficacy, and actually, if there is too much air in the line, the machine will

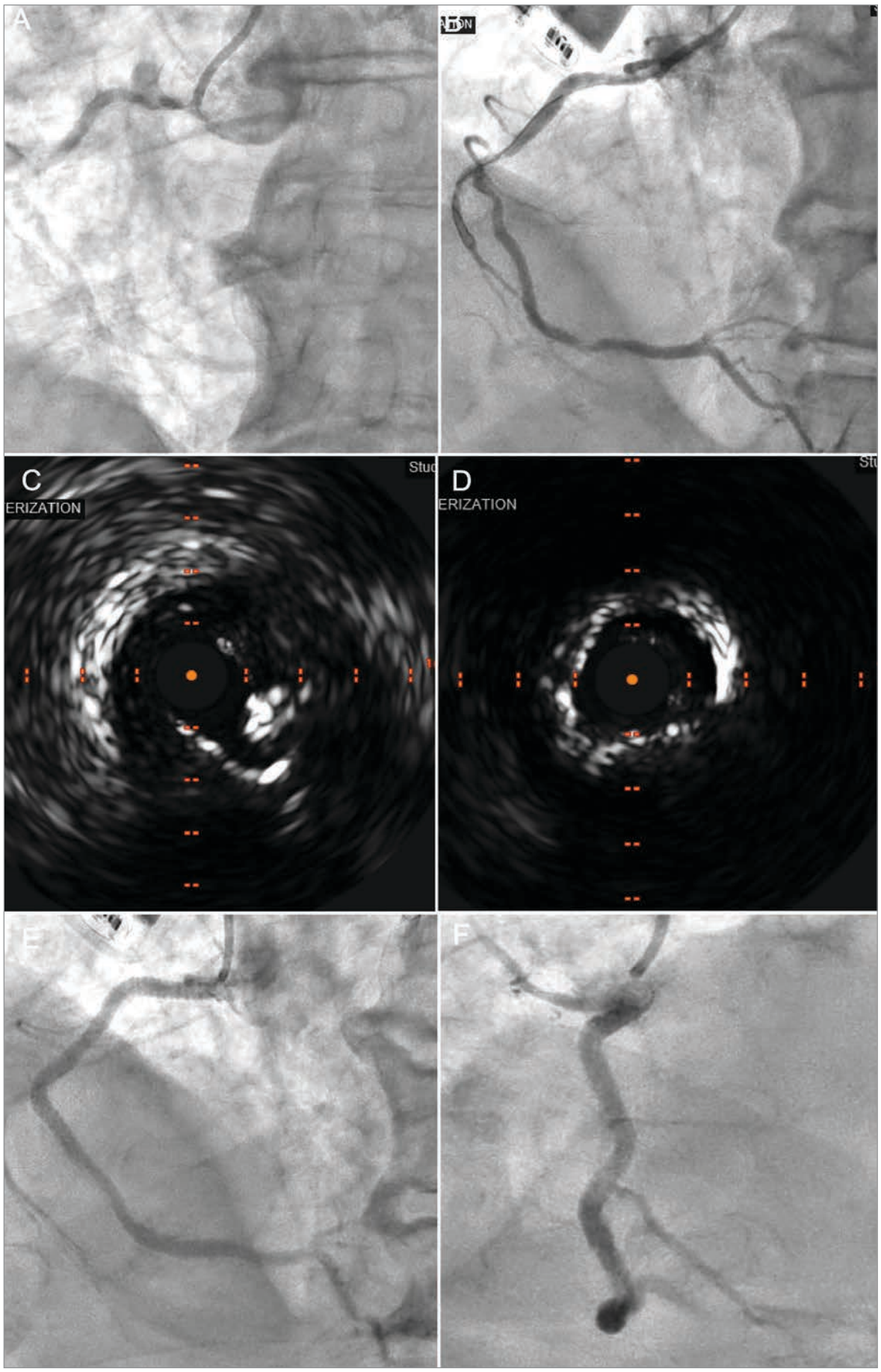

Figure 2. Efficacy of intravascular lithoplasty to treat aorto-ostial and proximal angulated right coronary artery (RCA) disease. (A) Baseline angiography showing a subtotal occlusion of the RCA. (B) Angiography after noncompliant balloon angioplasty of the aorto-ostial lesion, showing multiple calcific lesions in the proximal RCA as well as distal RCA. (C) Intravascular ultrasound of the mid LAD lesion. (D) Intravascular ultrasound of the aorto-ostial lesion. (E-F) Final angiography after IVL pre-treatment, and of the proximal RCA lesion and aorto-ostial lesions. Stenting was performed both distally and proximally, and at the aorto-ostial junction. The distal RCA lesion was predilated with a noncompliant balloon and responded well to this therapy. We could not advance the intravascular ultrasound at baseline through the proximal RCA lesion due to the severe calcification and tortuosity.

error (Error 88). I usually choose to do the prep myself, which does take a bit of extra time: 5 to 10 seconds negative pull 4-5 times. If you tell people to prep it like a valvuloplasty balloon, it will help, so that is a good tip.

Second, this is a device that is on the bulky side, so make sure you can get it to where you need to go. You cannot use the technique of edging the balloon up into a lesion, inflating it in hopes of cracking the lesion, and then move the balloon forward. This technique will not work with the IVL balloon. IVL requires you to treat distal to proximal, because after you inflate the balloon once, you are not going to get it back down. You can't negatively re-prep it and hope that it will cross a lesion. If your calcific lesion is proximal, get past it first and then treat. The use of Guidezillas (Boston Scientific) or guide extensions is something I would definitely recommend in order to help get that balloon past the lesion. Sometimes you do have to prep the lesion beforehand with a noncompliant or specialty balloon in order to get your IVL balloon down. You may have to use a combination of devices in order to be able to deliver the IVL device: atherectomy first, perhaps with a smaller burr or smaller spin, and then get your device down and treat with IVL. Obviously, the combination of atherectomy and IVL is not the most cost-effective approach, but sometimes necessary.

Third, when you are using IVL, there is an artifact that occurs on the EKG monitor. It is a pulsation of the sound energy that can look like IVL-induced ventricular capture. If you are not used to IVL and not prepared for it, this artifact can cause some angina amongst the staff. It looks like a pacer spike.

Finally, there is a connection piece from the generator to the catheter that is a separate piece. It can easily get misplaced, so it is very important to make sure that it stays with your main box generator. Ours is now strapped and bolted in place to make sure we don't lose it.

How often do you treat more than one lesion with IVL in a particular setting?

Routinely when it comes to tandem lesions in one vessel. When you are speaking about two vessels, it is a bit more complicated. I try to use one balloon to one vessel, because of the issue in delivering the IVL catheter to another vessel once the catheter is used. Sometimes if the lesions are proximal, as in our case example, you can deliver one balloon to multiple vessels. In that case, you want to start with the most angulated segment first, as shown in Figure 1, where we used the IVL on the circumflex first and then the left anterior descending coronary artery. Being a fiscal steward, you don't want to use two IVL catheters unless needed; sometimes that is what is necessary. Most of the time, I will try to use IVL for the more severe lesion and then treat the

other lesion with balloon angioplasty, depending on what is shown on intravascular ultrasound.

Has the new pass-through reimbursement changed your use of IVL?

The new coding definitely helps mitigate the cost-benefit ratio across the board. Reimbursement to just a balloon alone was not adequate enough to justify IVL use, so it absolutely helps to have a change in reimbursement. However, even though IVL is easy to use, fiscal responsibility demands that we use it only when necessary, meaning we shouldn't use IVL for every patient who has just a speck of calcium, because it is not responsible from a cost perspective. At the same time, I can tell you there are many cases that we could not do without IVL. The new reimbursement covered outpatients and as of October 1st, IVL will be covered for inpatients as well. This will help recoup the cost of the device for the hospital.

At what point in a procedure are you deciding to pull IVL off the shelf?

I call for IVL when I see concentric calcium on intravascular ultrasound, perhaps precluding the intravascular ultrasound from even passing, when I cannot get a noncompliant balloon to fully expand, and when I see calcium in an area that I feel is unsafe to perform atherectomy.

How do you go about applying the device's 80 pulses of energy in the vessel?

We use the whole pulse cycles in one vessel. When the catheter's 80 pulses are final, that is when we are done with the device. Sometimes it will be several runs in the same area. I will run through the 10 pulses that come in each cycle, timing the inflation and deflation so as to minimize coronary ischemia. I often will wait between runs to permit perfusion as needed, using the patient's symptoms and EKG to guide me.

Are you using intravascular imaging to view the results after applying IVL?

We, as a practice, use intravascular ultrasound for all of our coronary interventions. I generally use intravascular ultrasound before the case and absolutely after the case to make certain we have optimized our stent expansion. I do see the cracking and fracturing of the calcium on intravascular ultrasound when I repeat it after IVL. Generally, as I have become more comfortable with IVL, I skip this intravascular ultrasound run, follow with an noncompliant balloon, and then see how we are doing with vessel preparation on intravascular ultrasound. We have enough experience now with IVL use that I don't need to do intravascular imaging after every IVL use, but I still use it on every case.

Do you view IVL as a replacement for or complementary to current technologies?

IVL is another tool in the armamentarium that allows us to treat a very complex lesion subset. Can you use IVL as a complement to atherectomy? You can. If you can't get the device where you need it to go, use atherectomy first and then use your IVL balloon. IVL is going to become one tool in your toolbox to treat more challenging cases. The true benefit of IVL is in its safety profile. IVL is wonderful when you have so-called "rota regret", i.e., where after going up with your balloon, you see a waist which will not yield and now you also have a dissection. You can spend some time then trying to get that lesion to yield, using various balloons, as the dissection now precludes atherectomy. You would have to risk either putting in an underextended stent, which is never ideal, or bringing the patient back some other time. Now we have an option for those patients: IVL can help treat that lesion right on the table. You do not have to bring the patient back for a repeat procedure and face the risks that can occur with leaving a dissection in the coronaries.

Can you describe some scenarios where you have successfully used IVL in the coronary arteries?

I like to use IVL on aorto-ostial lesions (Figure 2). Ostial right coronary artery lesions are always a challenge, mainly because you have to make sure your guide is coaxial and the risk of aortic dissection is always present if you inject into the wrong area. Similarly, you can have a challenge in getting your atherectomy device to be coaxial. I have great appreciation for IVL use in this setting, because it allows us to safely crack the calcium and get good expansion of the lesion. The other subset is angulated, calcific lesions. I am thinking of one patient in particular, a surgical turndown, with a very angulated calcific, proximal circumflex where there was no absolute way we could get atherectomy around the bend safely without risking a perforation (Figure 1). In this patient, we were able to deliver

In the coronary realm, IVL allows us to treat in settings where otherwise it might not be possible, because it is an extremely safe technology. I think IVL is going to be used at hospitals without surgical backup, and maybe in ambulatory surgical centers, where PCI is now starting to be performed. We will see IVL applied across many different scenarios, because it offers a potential treatment option that is safe and effective.

IVL without an issue and treat the lesion safely. We got an amazing result with a 4 mm balloon, and eventually, good stent apposition. We will routinely use IVL for complex cases, any time where we have a challenge, especially if there is a risk with atherectomy. Aorto-ostial lesions and the torturous proximal circumflex bends are ideal places for IVL, as well as angulated bends in any vessel. These are tough areas to treat. In a vessel that is relatively straight, it is a toss-up between using atherectomy or IVL. But in an angulated segment that is heavily calcified, I think IVL is a game changer.

Any final thoughts?

IVL has also been a game changer when it comes to the peripheral space. As someone who also does a lot of peripheral intervention, it has just been amazing to watch. Cases get done now that otherwise couldn't get done.

The learning curve with this device for the staff comes down to really getting a good prep on the balloon. I bring this up again, because we got a call from our hybrid lab the other day where one of our vascular surgeons was using IVL and kept getting an error message. The device wasn't prepped adequately. Once we got it prepped, it worked fine. The importance of the device prep needs to be strongly communicated, because without the correct prep, you are not going to get the same efficacy.

Finally, in the coronary realm, IVL allows us to treat in settings where otherwise it might not be possible, because it is an extremely safe technology. I think IVL is going to be used at hospitals without surgical backup, and maybe in ambulatory surgical centers, where PCI is now starting to be performed. We will see IVL applied across many different scenarios, because it offers a potential treatment option that is safe and effective. Personally, I am not using as much atherectomy now as in the past, since the advent of IVL. Irrespective of device selection, heavily calcified vessels represent a higher risk lesion subset, and we must all be ever-vigilant for complications, including perforation, even with IVL. Not every case needs IVL, but some cases simply cannot be done without it. Using IVL is easy and it is an effective therapy indeed, but it is not the only therapy. The challenge is choosing the right device for the right patient at the right time. ■

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