Cath Lab Digest

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

CATH LAB SPOTLIGHT

University of Vermont Health Network - Champlain Valley Physicians Hospital (CVPH) Heart Center

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The University of Vermont Health Network - Champlain Valley Physicians Hospital (CVPH) is a 300-bed hospital in northern New York that is part of a 6-hospital network. The UVM Health Network - CVPH Heart Center in Plattsburgh, New York, was recently ranked as one of the top 100 hospitals in the nation for cardiac care and has been ranked among the top 10% in the nation since 2008. With quality as the bedrock of our heart program, our cardiovascular team uses the most advanced techniques to provide patients with the best possible care.

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Happy Cardiovascular Professionals Week!
February 13-19, 2022

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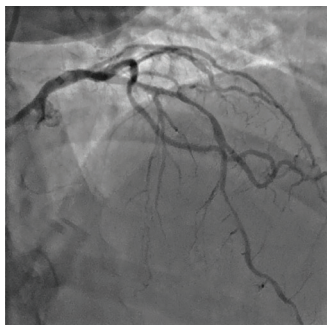
CALCIUM CORNER

Management of Calcified Lesions in Hospitals Without Surgical Backup

CLD talks with B. Clay Sizemore, MD.



You have a long experience performing percutaneous coronary intervention in a hospital without surgical backup on site. Can you share more about your practice?

Cardiovascular Consultants of South Georgia is a private practice cardiology group with nine cardiologists and 12 advanced practice providers (APPs). Our interventional partners operate out of three hospitals. Our main hospital is Archbold Medical Center in Thomasville, Georgia, with a busy coronary and peripheral program, along with device implants, and we are anticipating the addition of a full spectrum of electrophysiology procedures in the near future. This site does not have on-site surgical backup. Our interventionalists maintain privileges at Tallahassee Memorial Hospital, about 30 minutes down the road, which is our surgical backup facility. We do our high-risk cases at this hospital, including left main, atherectomy, and elective mechanical support cases. We also do cases at Colquitt Regional Medical Center, where we have an active peripheral program and growing cardiac diagnostic lab.

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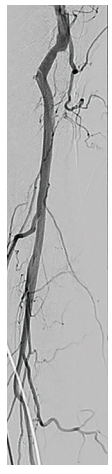
ATHERECTOMY

Leipzig's Experience Using Rotarex™ Rotational Excisional Atherectomy for In-Stent Reocclusion in Peripheral Arterial Occlusive Disease



CLD talks with Andrej Schmidt, MD, PhD.

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Management of Calcified Lesions in Hospitals Without Surgical Backup

CLD talks with B. Clay Sizemore, MD.

Archbold Medical Center, our primary site, was one of the leading enrolling sites in the C-PORT trial, the landmark trial that established the safety and benefit of percutaneous coronary intervention (PCI) without surgical backup. That trial was completed about 10 years ago, and upon completion, we applied to the state to do PCI without backup. Today, we essentially do all levels of coronary PCI at Archbold, with the exception of extreme high-risk cases. We cover six fairly rural counties. Access to a PCI center with moderate volume and great quality indicators is important to our region, particularly for ST-elevation myocardial infarction (STEMI) care, because otherwise, patients in those counties would require upwards of an hour transfer to the closest surgical backup site hospital. STEMI and access to other urgent cardiac care was actually the premise for the whole non-surgical backup movement. Non-backup programs are ubiquitous throughout Georgia and most states. The C-PORT trial and the experience of so many centers thereafter have really paved the way for the migration to outpatient PCI, with the next wave being the ambulatory surgical center (ASC) setting, establishing that PCI can be done safely with an exceptionally low incidence of urgent transfers for surgical services.

Patient selection has been an important part of our success. Calcium has long been a major issue. The original C-PORT protocol mandated that atherectomy and cutting balloon use be excluded from the trial, and as part of our application to the state of Georgia, we agreed to continue to apply a similar protocol for PCI case selection as was used in the trial. For patients who need calcium modification, we have historically taken them to the high-risk center and avoided doing them locally.

The beauty of intravascular lithotripsy (IVL) is that we now have an on-label calcium modifying tool with demonstrated safety; it is a therapy we can use without adding significant risk to the case. In addition, we are a default radial access lab, with about an 80% to 90% same-day discharge rate. We are big believers in same-day discharge and outpatient PCI, and IVL plays well into that.

During the COVID surge, patients were exceptionally avoidant of care and didn't want to get anywhere near the hospital. Telling them that they could come to the cath lab, where everyone was tested, and be sent home that same day, several hours later, without any exposure to the regular units or COVID wards, was a critical part of our keeping patients in the system so that they didn't avoid care, stay home, and have events. We know, unfortunately, that probably during COVID there was a lot of excess at-home mortality from people avoiding care. Creating pathways that allow patients to avoid overnight hospitalization is hugely beneficial to patients. It has always been convenient and a huge cost savings to the hospital, but is particularly important now, with staffing shortages. Our hospital now operates pretty much at or above capacity all the time with the nursing shortage. Not chewing up those resources unnecessarily is key and we do that by using a transradial approach with same-day discharge, proactively planned. We also do whatever we can to create safety and minimize complications. Having a perforation or a complication that requires hospitalization is one same-day discharge that was missed. IVL fits well in this strategy.

How has the safety of coronary IVL allowed for the treatment of calcium at your non-surgical backup center?

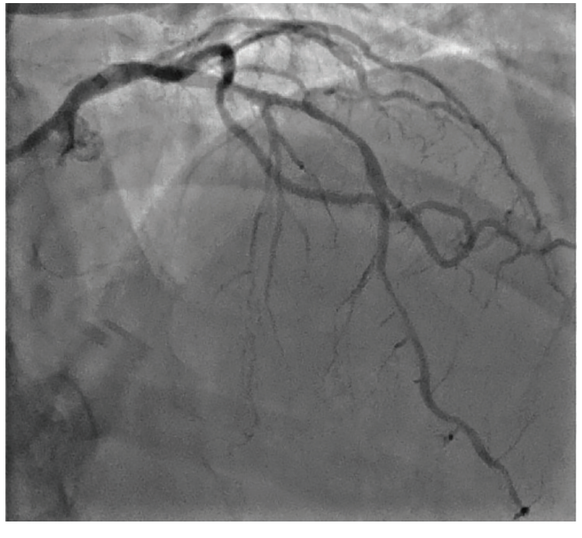

Figure 1. A 75-year-old female with non-ST elevation myocardial infarction (NSTEMI) with very heavily calcified diffuse tandem left anterior descending (LAD) coronary artery lesions. Intravascular ultrasound (IVUS) confirmed stenosis severity, showing a minimal lumen area (MLA) of 2.0 mm^2 with a dense arc of calcification (>180 degrees), but would not fully cross the proximal disease.

Figure 2. Pre-dilation of the more distal disease (and subsequently proximally) with a 2 mm x 30 mm noncompliant balloon. Note the "non-dilatable" nature of the lesion despite high pressure (16 atmospheres).

Figure 3. Intravascular lithotripsy (IVL) of the distal disease utilizing a 2.5 mm x 12 mm Shockwave balloon with a total of 8 cycles of 10 pulses to treat the entire segment.

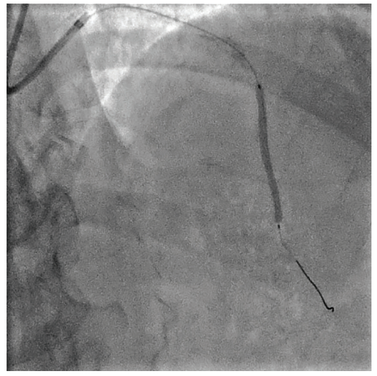

Figure 4. Deployment of a 2.25 mm x 38 mm drug-eluting stent (DES) in the mid-distal LAD.

Figure 5. IVL of the mid and proximal disease utilizing a 3 mm x 12 mm Shockwave balloon with a total of 8 cycles of 10 pulses to treat both segments.

Like all centers, we are using more and more advanced imaging, but it is not uncommon for a lesion to be unpredictably difficult to dilate and more heavily calcified than is readily apparent on angiography. In those situations, with a lesion that will not dilate, it is necessary to have a method by which to modify the calcium, even though its presence was not anticipated. This is a particularly precarious situation for operators in non-backup settings. In the past, we would use oversized, non-compliant balloons and take them to very high pressures trying to achieve an adequate final stent result. In exceptionally rare cases, a handful of times over my 10 years here, we would even abort the case mid angioplasty and have to transfer the patient in a less than entirely stable fashion to the high-risk center. Calcium was our Achilles' heel. We could always filter out the obviously high-risk cases, but there will always be a very small fraction of cases that do not have readily apparent calcium and are non-dilatable. IVL, from a safety standpoint, has been a game-changer for us not only in these cases, but also for cases with readily apparent calcium that otherwise would have required atherectomy. With the use of IVL, we are now at a point where the only cases that we have to either transfer or stage are non-crossable lesions: cases where you can get a wire but not a balloon across, and these are fairly rare.

All of our interventionalists are also active peripheral operators and already had experience with IVL use in the periphery. We found it to be an easy transition when coronary IVL was approved. We moved forward with trialing five coronary cases, which all went well. We have now been doing IVL in the coronaries for several months, with exceptionally good results. We were one of the first in south Georgia to bring IVL to clinical use in the coronaries. We are fortunate to have an administration that is focused on quality and safety. We were initially using IVL before there was a full pass-through for hospital reimbursement, and because of similar cost issues, we were generally using it very selectively in the periphery for extreme cases. We are very pleased with the Centers for Medicare and Medicaid (CMS) decision to improve hospital reimbursement for peripheral cases next year in addition to the recent pass-through language for coronary IVL use.

Can you share more about how the use of intravascular lithotripsy has changed your patient flow?

The presence of prohibitive calcium used to require a staging of the procedure, which happened one of two ways: we either transferred patients with the sheath in to the high-risk surgical backup site, or we completed the diagnostic case and staged the intervention on a different day. It was costly and inconvenient to both the patient and the provider. We entertained the possibility of bringing atherectomy to Archbold, but the problem is that most of the instructions for use (IFUs) for atherectomy catheters indicate that surgical backup should be part of the protocol, which we believed would make an application to the state for exemption challenging. Part of our consent process states that there are certain cases that we don't do because of risk. Patients seem to understand that, but very much want to stay local if they can. So while we do still tell the patients that there are a variety of issues that might arise that could require a transfer or staged procedure for their safety, calcium has become much less of a part of that conversation. The ability to use IVL has allowed us to reassure patients that their risk of transfer or staging is much lower. Whereas before IVL there was a 15 or 20% chance of needing to be transferred or staged, it is now a much lower percentage. The majority of our cases that we had to do at the high-risk center were for atherectomy, but IVL use has modified our

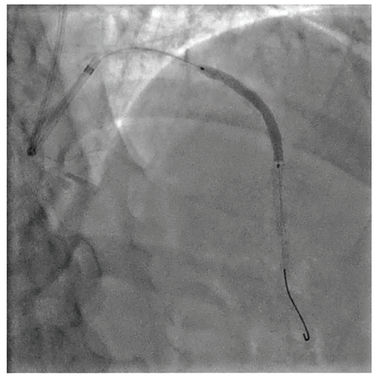

Figure 6. Deployment of a 2.75 mm x 38 mm DES in the mid vessel with subsequent post dilatation of the overlap site.

Figure 7. Deployment of a 3 mm x 34 mm DES in the proximal LAD, with subsequent post dilatation of the overlap site and post dilatation of the ostial-proximal segment utilizing a 3.5 mm x 25 mm balloon.

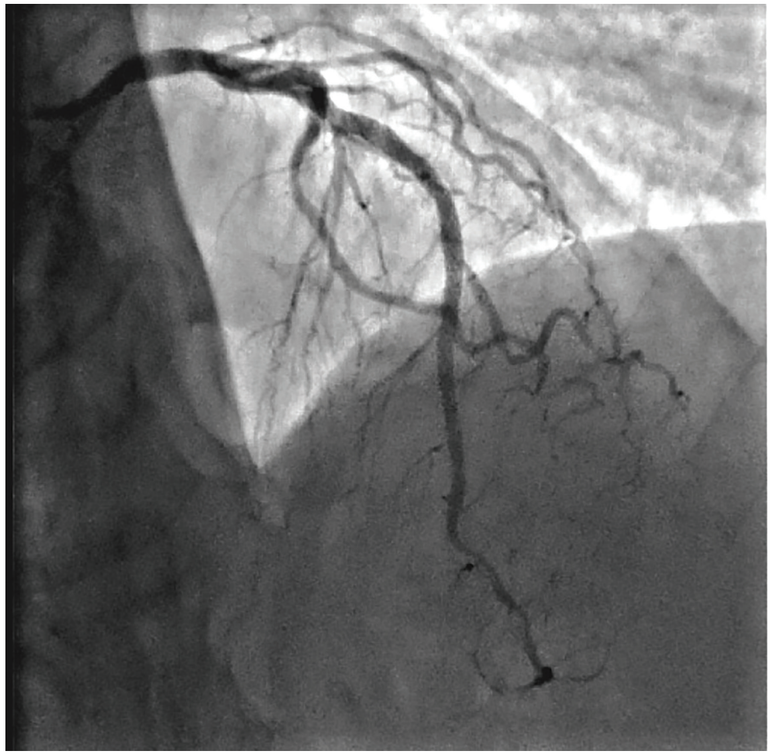

Figure 8. Final angiographic results demonstrating 0% residual stenosis and TIMI-3 flow.

expected transfer/stage rate substantially. This, in turn, creates an efficiency for the providers that also results in better access and availability for an underserved area, and has resulted in a beneficial halo effect in that regard.

The beauty of IVL use is that it is essentially an angioplasty, and does not require any more technical skill than a simple PCI. For operators that had previously transferred out patients to high-risk operators, their patients can not only stay local, but they also don't need to have a transfer of care. Patients keep the continuity of the same provider and the convenience of staying in their home facility. Our group is in somewhat of a unique situation in that we have a backup site partner that has been gracious enough to give us privileges and the hospital is close enough that we can actually do high-risk cases, even though it is not very efficient. I would suspect that the majority, or at least many, of non-backup hospitals instead simply transfer their patients to high-risk operators at tertiary or university centers. IVL is a huge coup for operators that don't do high-risk cases, because with IVL, they can now treat calcium without experience using high-risk techniques or a volume of cases that supports an advanced technology like atherectomy. IVL is not something that requires a significant learning curve like atherectomy. Even if you do a hundred or 75 cases a year, you are not going to have significant problems doing IVL.

IVL is a huge coup for operators that don't do high-risk cases, because with IVL, they can now treat calcium without experience using high-risk techniques or a volume of cases that supports an advanced technology like atherectomy.

While the extent of calcium might not be apparent on angiography, if you do see calcium, what happens next?

With the ability to more aggressively treat calcium here at our primary site with IVL, there has been a big uptick in our utilization of intervascular imaging such as intravascular ultrasound (IVUS). We are bringing in optical coherence tomography (OCT), with the idea that we will image a much higher fraction of our cases, because of this concept of unappreciated calcification. When we see either moderate or worse calcium, or have a recalcitrant lesion or lesion that is not dilating normally, we are quick to pull the IVUS imaging catheter out in order to assess the arc, length, and width of the calcium. Post IVL, we will generally reassess the lesion to confirm fracture of the calcium. We don't require IVUS post IVL for stenting, but it definitely is something that makes us feel good about moving forward with stent implantation. More and more, intravascular imaging is going to be a marketable quality indicator. If you are only doing a small percentage of intravascular imaging, I think you are going to be perceived as a lesser quality program. There has been a longstanding resistance to adopting a higher utilization of intravascular imaging, because of the combination of cost and time. I wish that CMS would see the benefit and create a situation where there are not negative financial incentives to doing imaging.

The ability to safely modify calcium at your center seems to be a net win for patients and providers.

Yes. IVL turns a difficult PCI into an easy PCI with a device that's easy to use and financially viable for the hospital. The safety issue can't be overemphasized. Cases that previously required the use of buddy wires, and secondary and tertiary balloons, add time and complexity. Balloon ruptures are also more frequent. You then have to use new balloons and the chance of having a complication such as a perforation goes up. All it takes is one perforation where you have to do a pericardiocentesis and salvage an emergency situation to see the value proposition of IVL. The cost of ambulance transfers and the cost of all the additional ancillary staff for a secondary procedure is also immense. Optimal procedural results also reduce readmission rates, which brings cost savings and quality improvement in terms of outcomes. IVL is a win across the board, for patients, providers, and administration.

What advice would you give to other centers without surgical backup who are just acquiring the technology?

Go for it. The clinical support staff with Shockwave is excellent, but frankly, has a fairly easy job, since the setup and operation of IVL is so straightforward. With CMS recognizing the benefit, creating pathways for financial viability, adding IVL is a no-brainer. Once you experience your first successful treatment of an unexpectedly non-dilatable lesion, you will know you made the right choice to bring in IVL. We are certainly enjoying, and our patients are enjoying, being able to stay close to home and get the best possible result for a good long-term outcome. ■

This article is sponsored by Shockwave Medical. Dr. Sizemore 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:

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