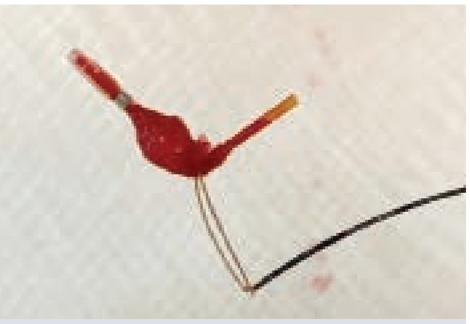
Cath Lab Digest

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



CASE REPORT

Thinking Creatively When Approaching Thrombotic Occlusions

George L. Adams, MD, MHS, FACC, FSCAI; Edward D. Tubberville, BS; Effie K. Lambrinos, BS

An embolus is defined as any substance (natural or unnatural) that can be entrapped within the vasculature of the bloodstream. Emboli of natural causes can be classified as any obstruction of fat deposit, air, or clot that causes a decrease in blood flow to a specific area within the body tissues. Additionally, foreign intravascular object embolization (FIOE) can be more inclusive, involving iatrogenic objects such as: intravascular catheter or wire embolization (ICWE) or an intravascular non-catheter object migration (INCOM), such as surgical stents, filters, and coils. Embolisms can cause a lack of blood flow resulting in tissue death if not retrieved within a short period of time.[1]

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In This Issue

CALCIUM CORNER

Data Show Coronary Intravascular Lithotripsy is Safe, Effective, and Cost Efficient

CLD talks with Margaret McEntegart, BSc (Hons), MBChB, MRCP (UK), PhD.

Editor's Note: This article PDF has been updated from the print version.

Dr. McEntegart discusses an analysis evaluating the cost effectiveness of coronary artery intravascular lithotripsy (Shockwave Medical) versus rotational atherectomy.

Can you tell us about your experience with coronary intravascular lithotripsy (IVL)?

IVL has been available in the United Kingdom (U.K.) since 2018. In fact, its initial usage was in a live case for the British Cardiovascular Interventional Society meeting in early 2019. The result was impressive and we were immediately persuaded that IVL was going to be a useful additional device. We started to use it for de novo calcific lesions. After an initial period of use, our institution, which is always conscious of cost, put a freeze on its use. Because the IVL device is so easy to use, they were worried 1everybody was going to start using it frequently in cases. In order to get it back on the shelf, we performed a cost analysis and provided data[1] to persuade the institution that IVL was going to be as cost-effective as competitor devices in the calcium space. Over the last two years, IVL has been consistently available to us and we have been using it in our practice to great effect.

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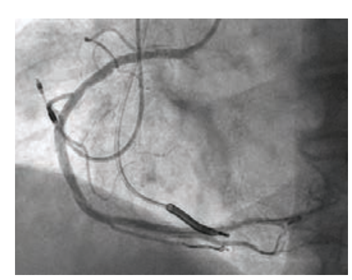
CASE REPORT

Proper Support: Right Coronary Artery Chronic Total Occlusion Treated Via a Bi-Radial Approach



Sergey G. Gurevich, MD

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Data Show Coronary Intravascular Lithotripsy is Safe, Effective, and Cost Efficient

What we were able to show was in fact that the IVL cases were cheaper than the rotational atherectomy cases, saving approximately £350-400 (USD$470-537) per case.

CLD talks with Margaret McEntegart, BSc (Hons), MBChB, MRCP (UK), PhD.

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How has your usage changed over time?

IVL was initially thought to be most helpful for concentric calcium, meaning arcs of calcium of greater than 270 degrees. We started out in our initial experience using IVL in focal, calcific lesions with large arcs of calcium, and then, as with all technologies, we started to use it in a wider morphology of calcific disease. IVL has dramatically increased the interventional cardiology community's use of intravascular imaging. People have paid greater attention to calcific disease, have been encouraged to learn how to analyze calcium, determine whether the use of a calcium modification device is needed, which device is most likely to be effective, and whether the device has done what was needed before stenting. As we started to increase our use of intravascular imaging in our cases, we learned that, in most patients, calcium is multi-morphology. For example, in a calcified left anterior descending (LAD) coronary artery, it is common to see some concentric segments, some eccentric segments, and minor or major protrusions of nodular calcium into the lumen. When we brought out IVL to deal with concentric calcium, we intuitively started to use it for the rest of the calcium in the vessel, so for the eccentric and the nodular calcium as well. Over time, we have become accustomed to using IVL in all modalities of calcium and also distributing the therapy over long segments of the vessel, as opposed to just focusing use on one lesion within the vessel. At the TCT 2021 meeting, optical coherence tomography (OCT) data was presented regarding the effectiveness of the device in both concentric and eccentric calcium, and showed that IVL was just as effective whether the calcium was concentric or eccentric.[2] These data confirm what we had started to do clinically, and I found it quite interesting as well as reassuring that our clinical judgment is backed up with a detailed evidence base.

Tell us about the research you have performed with coronary IVL.

I have been involved in a few studies. We did a cost-effective analysis with the data from Disrupt CAD II, the second IVL observational study in Europe, looking at the cost per case and comparing it to 60 rotational atherectomy patients we had done in our institution.[1] We blindly adjudicated the rotablation cases to confirm they would have been suitable for IVL or rotablation, and then compared the costs of the procedures. What we were able to show was in fact that the IVL cases were cheaper than the rotational atherectomy (RA) cases, saving approximately £350-400 (USD$470-537) per case. Our analysis was not only persuasive for the institution to allow us to use IVL, but when we dissected the data as to why IVL cases were less expensive, we found that it was because less additional equipment was used: fewer wires and fewer balloons. So it seems that If you use IVL in certain cases, it will facilitate a reduction in other procedural costs. IVL use also shortened procedure duration, which obviously adds to the cost effectiveness as well. It's important to caveat the conclusions with the fact we were comparing real-world RA cases to clinical trial IVL cases. We have also looked at IVL use in chronic total occlusions (CTOs)[3], vein grafts[4], and in ST-elevation myocardial infarction (STEMI)[5]. These are small cohorts with an initial experience. We also have looked at a cohort of patients with in-stent restenosis.[6] We published a series of small, observational studies of our initial use in all these different settings where we have found IVL to be helpful, and looked at effectiveness and safety in each of those cohorts.

Did you only look at rotational atherectomy versus IVL, or were there any other types of calcium modification devices that you reviewed in your research?

We only looked at rotational atherectomy, because orbital atherectomy only became available in the U.K. and Europe this past fall. It is one of those situations where, due to regulatory authorities and market availability, the U.K. has had the ability to use IVL for three years, and the United States has had orbital atherectomy available for a several years, and now almost simultaneously both devices are available to everyone. Laser, the other atherectomy device, is only used in limited centers in the U.K. and Europe; in the U.K., there are maybe three centers with laser and the usage is very low. Our calcium modification devices are rotational atherectomy, cutting balloons, scoring balloons, OPN high-pressure balloons (SIS Medical), and now IVL.

Would you want to compare specialty balloons to IVL?

Most people feel that cutting balloons and scoring balloons are better when you are dealing with more moderate, lower-complexity calcium, or fibrocalcific disease, whereas when there is severe calcium, most people will use an atherectomy device or IVL. In the PREPARE-CALC study, a randomized trial done in Germany, they compared rotational atherectomy to scoring balloons. We were keen to compare IVL to rotational atherectomy, however, because we wanted to compare the two modalities for calcium modification at the more severe end of the spectrum.

Your research showed that IVL cases used fewer wires and other equipment as compared to rotational atherectomy. Why is that?

In a rotational atherectomy procedure, we usually pass a wire through the lesion, then use a microcatheter on that first wire to exchange out and deliver the rotawire, which is a difficult wire to deliver down a diseased coronary artery. So if you have a calcific lesion, it is often easier to use a better crossing wire, take a microcatheter over that wire, take the wire out, and then put the rotawire through the microcatheter. Already, you are using two wires and a microcatheter. Then you do rotational atherectomy and when it is finished, the first wire or a 3rd support wire is put back down. You will use a non-compliant balloon (at least one, maybe two) to dilate the lesion before placing the stent. By this point, you have already used two or three wires, at least a couple of balloons, and the microcatheter. Whereas with IVL, you put one wire down, put the IVL down, treat the lesion, maybe use a non-compliant balloon, and put in your stent. It is that ability to deliver the device on any wire, and dilate the lesion and modify the calcium with one piece of equipment, that makes it more efficient, which is also why the

IVL procedure is shorter. If you look at wire and microcatheter costs, you can quickly see where the £400 savings comes from in our cases.

How does delivery of IVL compare to the delivery of a rotational atherectomy device?

The reason that every cath lab has to have rotational atherectomy is that it can cross any lesion. It is a forward-modifying ablative device and will cross what we call 'uncrossable' lesions. A lesion that nothing else will cross, the rota will eventually burrow its way through. The delivery of it and the calcium modification are the same process. In terms of IVL, from the outset, I was pleasantly surprised, even with the first generation of the device, with how deliverable it was. Certainly the second iteration of the device is considerably more deliverable than the first. In the majority of cases, the ability to deliver the IVL device, even down to the mid to distal vessel, is consistent. If IVL is difficult to deliver, I will use a guide extension. I will take a smaller balloon down to the target lesion and anchor it — inflate it in the vessel. With that balloon anchored, I deliver the guide extension down to that location, deflate and remove the balloon, and then deliver the IVL straight to the lesion. It is a very effective way to overcome any issues with deliverability, but we don't require to use this method routinely. In fact, these cases tend to be ones where you still need a guide extension to get a stent in, meaning that even if you didn't need the guide extension to deliver the IVL, it would still be needed to deliver the stent. You are not losing anything in this scenario by using the guide extension, because it then goes on to be helpful for the rest of the case, both to get in your stent and then the post-dilatation balloons. It is more often the case that dictates the need for a guide extension, as opposed to it being a limitation of the IVL device. In most of these cases, even if you had performed rotational atherectomy, there is a good chance you would still need the guide extension to deliver the stent.

How has your analysis of IVL changed your use of the technology and what do you see going forward?

Working in the U.K., it is obviously a cost constraints environment. We do a high number of CTOs, complex percutaneous coronary interventions (PCIs), including lots of calcific disease, so for each case, I am very aware of the cost of every single device I take off the shelf. Every time I decide to use something, I am thinking about whether I really need it. Is it a good use of resources? The data we collected resulted in me being happier with the decision to use IVL upfront in cases where we are dealing with moderate to severe calcium, because I knew it was going to ultimately be cost effective, as opposed to causing cost issues. Our research has encouraged me and the rest of our group to use IVL more readily, with our usage of IVL versus rotational atherectomy having shifted significantly. I think this is in part also due to IVL being much easier to use for less experienced operators than the atherectomy devices.

Can you describe your center?

I work at the Golden Jubilee Hospital in Glasgow. We are a high volume PCI center and doing over 3000 PCIs per year, approximately 700 STEMIs, about 60% non-STEMI work, and the rest is elective work. We have 12 operators, with more than half of the operators doing complex work. In addition to high volume left main, calcium, and CTOs, we do transcatheter aortic valve replacement (TAVR), MitraClip (Abbott Vascular), adult congenital interventions, and are the national transplant center.

The Golden Jubilee Hospital is a regional center that covers the whole of the west of Scotland. Scotland is a small country with a population of five million people with quite an interesting setup, as we only have five PCI centers. Glasgow's the biggest city, with the biggest surrounding density of population, so out of hours, on call, we cover a population of approximately two million people for STEMI. It is a big, busy center and we see a lot of calcific coronary disease. Especially as the population is aging, we are seeing more and more complex and calcific disease.

IVL technology is incredibly easy to set up and use. It has made management of calcific disease very accessible for all PCI operators. While in the past, there were frequently cases you would refer on to the higher-volume, complex operators or centers in your region, IVL allows patients with calcific disease to be more readily treated by their own interventional cardiologists.

What is your message for interventionalists who may not be using IVL or who have just begun using this device?

The key message is that IVL technology is incredibly easy to set up and use. It has made management of calcific disease very accessible for all PCI operators. While in the past, there were frequently cases you would refer on to the higher-volume, complex operators or centers in your region, IVL allows patients with calcific disease to be more readily treated by their own interventional cardiologists. It has lowered the complexity of managing these cases, and certainly from the initial safety data from the Disrupt CAD studies it looks incredibly safe, with a very low complication rate. I think IVL is practice-changing, and most importantly, it is a strong driver towards improved patient management.

You note IVL might allow patients to be treated by their own interventionalists rather than being referred. Have you seen that happening?

Yes. Our setup is unique in that we provide a regional hub service, so all the cases come to our center; there are no outlying PCI centers. But, within our center, what has happened is that some of the operators who previously wouldn't have done calcium cases at all — they would have referred the patient on within the center to someone else — have started handling calcium cases themselves, because they are very comfortable using IVL. I have scrubbed in with a few for one or two cases just to show them how to set up the IVL, and then that's it, they are off and running. Sometimes on call, nighttime or weekends, you get an acute case that is calcified. In the past, these operators would have struggled with such cases, and maybe had to take the patient off the table to wait through the weekend. With the use of IVL, they are now able to deal with most of these case themselves. In our group, everybody is now proficient in using the IVL device, whereas with rotational atherectomy, maybe two-thirds of the group are confident and proficient in using it. IVL streamlines patient management, and also, I think is good for team dynamics as everybody feels that they are part of progress and can retain ownership of their work. IVL has helped level the field, which is great. That's what technology is meant to do, isn't it?

Any final thoughts?

The main message is that the IVL device is very simple and easy to use. It makes the treatment of patients with calcific disease more accessible to operators. Certainly, the safety profile looks very reassuring from the initial data from the studies. That is everything you could really want from a new technology in the space. Shockwave Medical should also be rewarded for driving forward, almost without intending to do so, our knowledge and understanding of calcific coronary artery disease. The use of IVL has forced us to look more closely at and think about the best way to treat calcific coronary artery disease, and ask which device is better in which situation. The advances in our understanding of calcific coronary disease, with the paralleled increased use of intravascular imaging, have accelerated in the last couple of

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years and will continue to do so with the huge number of research projects that are now ongoing in this territory. Previously, calcific coronary disease was under-studied, whereas now there has been an explosion of interest.

Do you have plans for any further studies going forward?

At TCT 2021, there was an interesting gender sub-analysis of the IVL Disrupt CAD data.[7] In Glasgow, we had previously looked at gender-based outcomes for rotational atherectomy. We had a registry of over 700 patients treated with rotational atherectomy, and we analyzed male versus female complications and outcomes. We observed that with rotational atherectomy, women had significantly higher complication rates than men. The sub-study looking at male versus female outcomes with IVL from the Disrupt CAD data showed no difference and that the complication rate was low in both groups. Following on from this we have plans for some ongoing studies to look at the different calcium modification devices and compare them according to gender. One of the things we are starting to understand about coronary disease in general is that male and female patients, disease patterns, and response to treatment is different. Our plans are to look at whether the morphology and pattern of calcium within men and women is different. Do women have more nodular or more concentric calcium? By understanding this it may guide us to use different approaches to treating coronary artery calcium in the different genders. ■

References

1. Rishad S, McEntegart M, Ford TJ, et al. Comparative study of costs and resource utilisation of rotational atherectomy versus intravascular lithotripsy for percutaneous coronary intervention. *Minerva Cardiol Angiol.* 2021 Nov 11. Epub ahead of print. doi: 10.23736/S2724-5683.21.05681-7
2. Maehara A. Cracking the nodular code. In: Coronary intravascular lithotripsy (IVL): research roundup at TCT with Drs. Dean Kereiakes, Ziad Ali, Akiko Maehara, and Yasin Hussain. *Cath Lab Digest*. 2021 Dec; 29(12). Available online at https://www.cathlabdigest.com and at https://blog.shockwavemedical.com/q-and-a-akiko-maehara-coronary-ivl-nodular-calcium-at-tct21
3. Øksnes A, Cosgrove C, Walsh S, et al. Intravascular lithotripsy for calcium modification in chronic total occlusion percutaneous coronary intervention. *J Interv Cardiol.* 2021 Jun 21;2021:9958035. doi: 10.1155/2021/9958035
4. Øksnes A, McEntegart M. Intravascular lithotripsy in saphenous vein grafts and graft stent failure: A case series. *Catheter Cardiovasc Interv*. 2021 Jun 1; 97(7): E945-E950. doi: 10.1002/ccd.29265
5. Cosgrove C, Hanratty CG, Hill JM, et al. Intravascular lithotripsy for treatment of calcific coronary lesions in ST elevation myocardial infarction. Catheter Cardiovasc Interv. 2021 May 29. Epub ahead of print. doi: 10.1002/ccd.29801
6. Yeoh J, Cottens D, Cosgrove C, et al. Management of stent underexpansion using intravascular lithotripsy-defining the utility of a novel device. *Catheter Cardiovasc Interv*. 2021 Jan 1; 97(1): 22-29. doi: 10.1002/ccd.28715
7. Hussain Y. Gender equality in treating calcium. In: Coronary intravascular lithotripsy (IVL): research roundup at TCT with Drs. Dean Kereiakes, Ziad Ali, Akiko Maehara, and Yasin Hussain. *Cath Lab Digest.* 2021 Dec; 29(12). Available online at https://www.cathlabdigest.com and at https://blog.shockwavemedical.com/q-and-a-yasin-hussain-coronary-ivl-men-vs-women-at-tct21

This article is sponsored by Shockwave Medical. Dr. McEntegart 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 directly access the Calcium Corner.

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EDITOR'S PICKS

JOURNAL OF Invasive Cardiology

Feasibility and Clinical Outcomes of 48 mm Drug-Eluting Stents in the Management of Patients With Coronary Artery Disease

Ahmed Mahmoud El Amrawy, MD; Mohamed Ibrahim Loutfi, MD; Salah Mohamed El Tahan, MD; Sherif Wagdy Ayad, MD

This prospective study enrolled 300 patients, with a single CAD planned to undergo PCI with 48 mm DES. Clinical data, procedural outcomes, and follow-up to 6 months were obtained. Major adverse cardiac events were considered the combined study endpoint, defined as cardiac death, non-fatal myocardial infarction, unstable angina, and the need for target-lesion revascularization.

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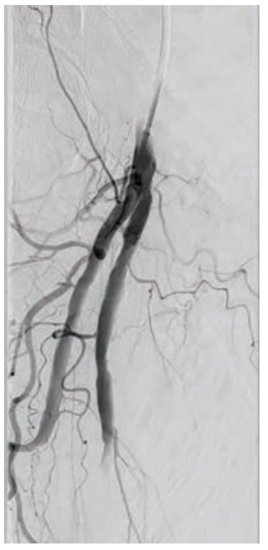
VDM Vascular Disease Management

Back to Basics: Arterial Sheath Management

Erica Fidone, MD; Justin Price, MD; Craig Walker, MD



Operators must quickly recognize complications and provide management options for each one. We present the case of a clotted femoral arterial sheath that was promptly recognized and corrected prior to the development of potentially catastrophic complications.

Vascular Disease Management 2021;18(12):E223-E227
vasculardiseasemanagement.com