

Cath Lab Digest

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



TRANSRADIAL HEMOSTASIS

Comparison of Two Methods for Transradial Hemostasis After Cardiac Catheterization and Impact on Post-Procedure Efficiency

Jane Meitler, MSN, RN, ACNS-BC, CV-BC;
Theresa Briggs, MSN, RN, RCIS;
Amanda Sedacki MSN, RN, CV-BC;
Jeanne Hlebichuk PhD, RN, NE-BC

Transradial access (TRA) for invasive cardiac catheterization procedures has increased over the last decade.¹ According to the National Cardiovascular Data Registry, the practice of TRA for percutaneous coronary intervention procedures increased from 16.1% in 2012 to 53.7% in 2021.² Despite this rapid increase in TRA utilization, the United States still lags behind other countries.³ Research has shown that use of radial access offers earlier mobilization, less risk of kidney injury, decreased mortality, and shortened length of stay as compared to the transfemoral approach.⁴

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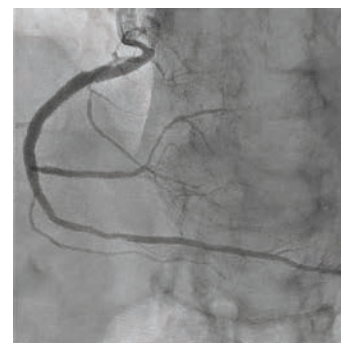
CALCIUM CORNER

An “IVL-First” Strategy Using 120 Pulses With the Next-Gen C²⁺ Shockwave Catheter

CLD talks with Brian K. Jefferson, MD.

What has been your experience with intravascular lithotripsy (IVL) and the Shockwave C²⁺ catheter?

We have used Shockwave IVL since its commercial launch in the United States, so we have a long experience with the use of IVL for calcium modification. The new C²⁺ IVL catheter offers fifty percent more pulses, for a total of 120, and these extra pulses often come in handy. Having 40 extra pulses allows us to treat lesions that in the past might have been too diffuse or too long for single-catheter IVL use, and we also can use the extra pulses in the C²⁺ to treat lesions in more than one vessel. In multiple cases, we have now been able to use a single IVL catheter in two vessels or in lesions where we might have previously used atherectomy due to pulse limitations.



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NEW TECHNOLOGY

Talking to TCT 2023's Shark Tank (Innovation) Competition Winner: HeartPoint Global's IntelliStent is an Adjustable, Multilumen Stent System for Pulmonary Hypertension in Congenital Heart Disease

CLD talks with Elena Amin, MBChB, pediatric interventional cardiologist at the University of California, San Francisco, and a member of HeartPoint Global's Advisory Board, and HeartPoint Global Chairman and CEO Seth Bogner.

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An “IVL-First” Strategy Using 120 Pulses With the Next-Gen C²⁺ Shockwave Catheter

CLD talks with Brian K. Jefferson, MD.

Can you describe the lesions where you use IVL?

We use IVL in lesions with evidence of severe calcification, either angiographically or by using other forms of imaging like intravascular ultrasound (IVUS) or optical coherence tomography (OCT). Often these complex lesions lead to issues with stent delivery and optimization. IVL has been shown to be a safe and efficient way to modify calcium before stenting. Other forms of traditional calcium modification such as orbital or rotational atherectomy have an elevated risk profile and many people are hesitant to use them because of the risk involved, especially if surgical backup is not

available. Having a safe mechanism available like IVL allows us to more effectively treat patients with severely calcified lesions.

How are you changing your pulse management strategy with the additional 40 pulses of the Shockwave C²⁺ catheter?

Because of the limitations of the prior catheter, we developed several strategies for pulse conservation with IVL. One option is using intravascular image guidance as a way to target areas of severe calcification for treatment. For example, OCT has built-in algorithms to determine the depth and

degree of the arcs of coronary calcium. We can employ these algorithms to help focus therapy on those diseased areas. Similarly, we can use IVUS to identify areas where there is concentric or nodular calcium that would potentially need modification, and spare therapy in less diseased sections of the artery.

Sometimes identifying areas for treatment is as simple as inflating the IVL balloon. At 4 atmospheres, if you are able to get full expansion of the balloon, then that area may not benefit as much as areas without expansion. Subsequently, after IVL treatment, I dilate with a 1:1 noncompliant (NC) balloon that is the size of my stent to ensure I have full expansion. If not, I focus more pulses in that area to ensure full stent expansion.

Another area where we were limited by pulses previously was using IVL in two separate vessels. There have been times when I was in a second vessel with moderate to severe calcium but had already used all of therapy in a catheter. I tried to not use IVL in these scenarios, being economically conscious, but with the extra pulses of the C²⁺, treating a second vessel with IVL and having enough pulses is no longer as big of a concern. While some of the previous economic concerns have been alleviated with the coding changes supporting IVL reimbursement, now with the extra 40 pulses, you often have enough pulses to treat two vessels using a single catheter.

Are there cases where you might have considered atherectomy first, or something else to modify the calcium, but now with the 40 additional pulses, you are thinking about IVL first?

I think of IVL first, period, just because of the lower risk profile of IVL versus other forms of calcium modification. It is a simple balloon-based therapy versus mechanical atherectomy, whether rotational or orbital, which carry a higher risk of perforation or dissection, and are technically more cumbersome to perform. When we started using IVL, many of us first thought we were going to need to use mechanical atherectomy in order to deliver the IVL balloon. However, the balloon is a great deal more deliverable than we initially thought. In our institution, we use a rota-shock or rota-tripsy paradigm in less than 10% of cases.

Also, IVL's mechanism modifies calcium differently compared to other modalities. Rotational atherectomy modifies superficial calcium and doesn't affect the deeper calcium, and is somewhat limited on burr size. Orbital atherectomy may have some modification of deeper calcium due to the nature of its mechanical forces. But, again, the risk profile is higher compared to IVL, so I still prefer to use IVL up front.

I use an IVL-first strategy and reserve mechanical atherectomy mostly for cases when I just can't deliver the balloon. When I see severe calcium, the first decision is how I am going to safely modify it, independent of the pulse limitations.

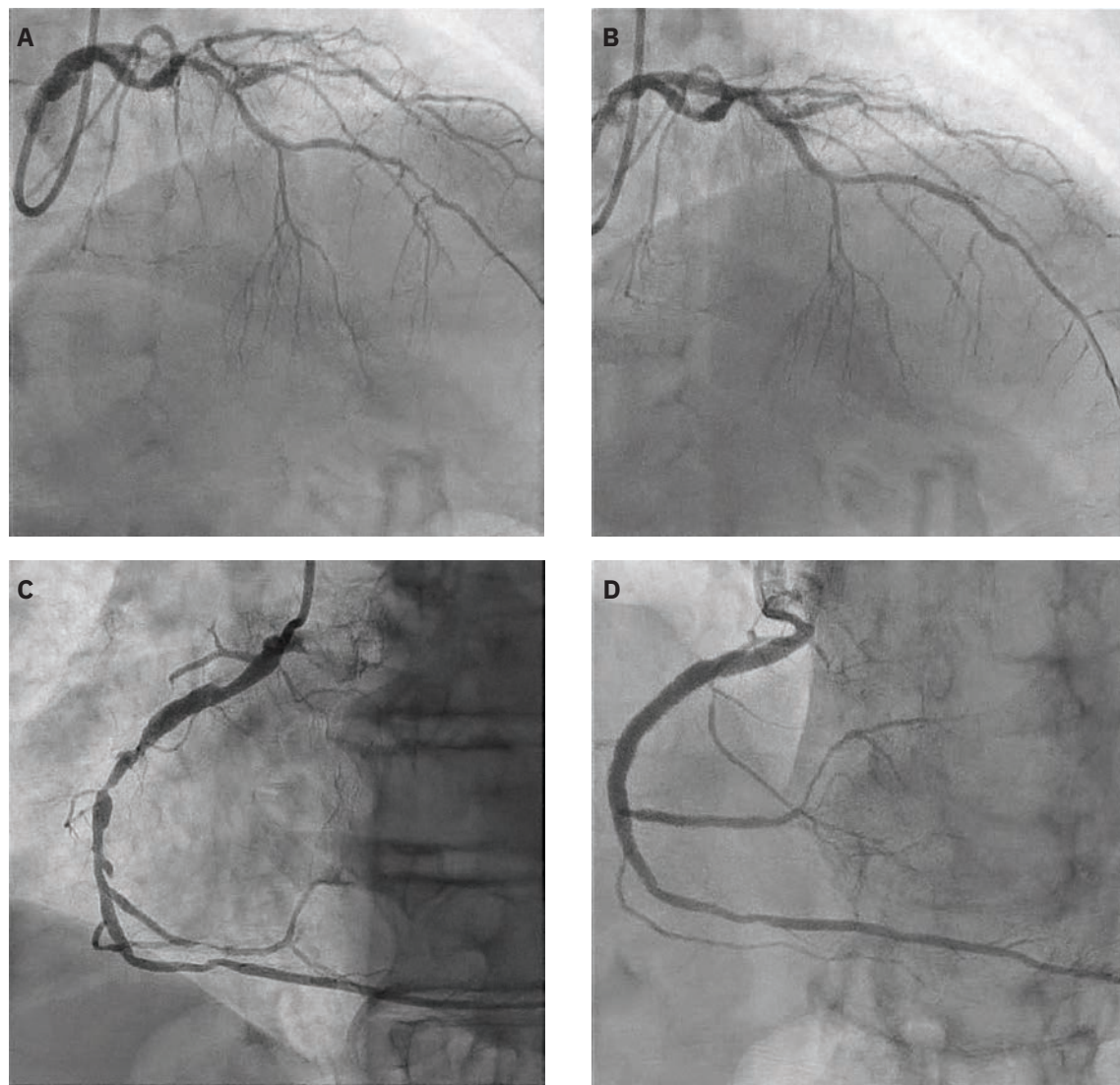


Figure 1A-D. Use of a Shockwave C²⁺ IVL catheter in multiple vessels. (A) Baseline angiogram of a diffusely diseased left anterior descending (LAD) coronary artery. A 3.5 mm C²⁺ catheter was used with 40 pulses delivered across the proximal LAD and (B) successful placement of two drug-eluting stents. The remaining pulses in the IVL catheter were then delivered into the (C) right coronary artery with subsequent (D) successful drug-eluting stent placement.

Bookmark CLD's Calcium Corner online to read more from Drs. Ali, Kereiakes, McEntegart, Khatri, and more:



The key advantage to the greater number of pulses with the C²⁺ is our ability to treat longer, more diffuse lesions and multiple vessels with a single catheter, both limitations in the past. The C²⁺ is the same profile and cost as the first-generation C² catheter. Quite simply, more is better and leads to additional benefits of therapy.

The additional pulses allow us to treat longer and more lesions while maintaining this IVL-first strategy.

Can you comment on how the radial approach might impact delivery of the IVL balloon?

Even though radial access penetration in the U.S. is pretty high, for more complex cases, the use of that approach tends to be lower among operators. Traditionally, a 6 French (Fr) radial approach has been limited by guide size for equipment delivery and support in the more complex cases. While a 7 Fr radial guide can be used, in some patients there are some limitations due to radial artery caliber, especially in women. To overcome this, many experienced operators will still use a femoral approach for more complex cases or maybe a single-access Impella (Abiomed) approach where you can use a 7 Fr guide catheter.

At our institution, IVL has allowed us to maintain the benefits of a radial approach for even the

most complex cases. The IVL system can usually be delivered via a 6 Fr guide, utilizing a guide extension if needed. This allows us to treat disease that historically might have required a larger sheath and femoral approach. IVL is a large part of how that is possible.

How do you think the extra pulses with the C²⁺ will change calcium modification in the cath lab?

A lot of people have adopted IVL, but one of the limitations has been the number of pulses available in a single catheter. Fifty percent more pulses allows us to treat more lesions or even more thoroughly modify a single lesion. This ultimately will lead to more successful stent optimization and outcomes.

Any final thoughts?

When I look at transformative technologies IVL is one of the more significant tools to impact

my practice. It allows us to improve outcomes in complex patients with lower risk. The key advantage to the greater number of pulses with the C²⁺ is our ability to treat longer, more diffuse lesions and multiple vessels with a single catheter, both limitations in the past. The C²⁺ is the same profile and cost as the first-generation C² catheter. Quite simply, more is better and leads to additional benefits of therapy. ■

Shockwave Medical sponsored this interview and Dr. Jefferson is a paid Shockwave Medical consultant.

Brian K. Jefferson, MD, FACC, FSCAI

Centennial Heart

HCA Tristar Centennial Medical Center
Nashville, Tennessee



Shockwave C²⁺ 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, anti-coagulant and/or antithrombotic therapy-Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion-Cardio-pulmonary 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 nonemergency coronary artery bypass surgery-Emergency or nonemergency 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.

SPL-70789 Rev.A